

ANIKA THERAPEUTICS INC  
Form 10-Q  
November 09, 2010

---

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

---

FORM 10-Q

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

For the quarterly period ended September 30, 2010

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

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

Commission File Number 000-21326

Anika Therapeutics, Inc.  
(Exact Name of Registrant as Specified in Its Charter)

Massachusetts  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

32 Wiggins Avenue, Bedford, Massachusetts  
(Address of Principal Executive Offices)

01730  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (781) 457-9000

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report: N/A

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller  
reporting company)

Smaller reporting  
company

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

As of November 8, 2010, there were 13,481,325 outstanding shares of Common Stock, par value \$.01 per share.

---

---

---

PART I: FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiaries  
Condensed Consolidated Balance Sheets  
(unaudited)

ASSETS	September 30, 2010	December 31, 2009
Current assets:		
Cash and cash equivalents	\$ 25,765,924	\$ 24,426,990
Accounts receivable, net of reserves of \$272,723 at September 30, 2010 and \$29,261 at December 31, 2009	14,729,937	11,778,743
Inventories	9,395,081	8,547,339
Current portion deferred income taxes	2,215,930	2,228,291
Prepaid expenses and other	2,039,871	2,892,858
Total current assets	54,146,743	49,874,221
Property and equipment, at cost	48,791,574	47,172,403
Less: accumulated depreciation	(12,371,651 )	(11,424,788 )
	36,419,923	35,747,615
Long-term deposits and other	397,252	413,228
Intangible assets, net	30,375,165	33,577,451
Deferred income taxes	1,524,110	3,506,362
Goodwill	6,990,157	7,488,036
Total Assets	\$ 129,853,350	\$ 130,606,913
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 9,164,823	\$ 6,354,761
Accrued expenses	4,864,825	5,816,170
Deferred revenue	2,700,000	2,751,467
Current portion of long-term debt	1,600,000	1,600,000
Total current liabilities	18,329,648	16,522,398
Other long-term liabilities	1,625,365	1,775,386
Long-term deferred revenue	6,074,995	8,099,996
Deferred tax liability	7,845,258	9,265,631
Long-term debt	11,600,000	12,800,000
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at September 30, 2010 and December 31, 2009		
Common stock, \$.01 par value; 30,000,000 shares authorized,	-	-
13,481,303 shares issued and outstanding at September 30, 2010 and	134,813	134,188

13,418,772 shares issued and outstanding at  
December 31, 2009

Additional paid-in-capital	61,605,044	60,539,768
Accumulated currency translation adjustment	(1,796,614 )	-
Retained earnings	24,434,841	21,469,546
Total stockholders' equity	84,378,084	82,143,502
Total Liabilities and Stockholders' Equity	\$ 129,853,350	\$ 130,606,913

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

Anika Therapeutics, Inc. and Subsidiaries  
Condensed Consolidated Statements of Operations and Comprehensive Income  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Product revenue	\$ 13,179,399	\$ 10,087,130	\$ 38,542,378	\$ 27,376,966
Licensing, milestone and contract revenue	689,815	705,634	2,292,723	2,139,798
Total revenue	13,869,214	10,792,764	40,835,101	29,516,764
Operating expenses:				
Cost of product revenue	6,108,502	3,551,374	17,123,930	10,057,200
Research & development	1,774,623	2,382,146	5,486,920	6,862,683
Selling, general & administrative	3,908,452	2,842,991	13,164,775	8,613,525
Total operating expenses	11,791,577	8,776,511	35,775,625	25,533,408
Income from operations	2,077,637	2,016,253	5,059,476	3,983,356
Interest income (expense), net	(39,888 )	(44,096 )	(149,095 )	(44,038 )
Income before income taxes	2,037,749	1,972,157	4,910,381	3,939,318
Provision for income taxes	853,485	460,232	1,945,086	948,899
Net income	\$ 1,184,264	\$ 1,511,925	\$ 2,965,295	\$ 2,990,419
Basic net income per share:				
Net income	\$0.09	\$0.13	\$0.23	\$0.26
Basic weighted average common shares outstanding	12,633,405	11,385,679	12,615,705	11,379,128
Diluted net income per share:				
Net income	\$0.09	\$0.13	\$0.22	\$0.26
Diluted weighted average common shares outstanding	13,622,603	11,575,907	13,598,886	11,535,721
Net income	\$ 1,184,264	\$ 1,511,925	\$ 2,965,295	\$ 2,990,419
Other comprehensive income (loss)				
Foreign currency translation adjustment	3,082,286	-	(1,796,614 )	-
Comprehensive income	\$ 4,266,550	\$ 1,511,925	\$ 1,168,681	\$ 2,990,419

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

Anika Therapeutics, Inc. and Subsidiaries  
Condensed Consolidated Statements of Cash Flows  
(unaudited)

	Nine Months Ended September 30,	
	2010	2009
Cash flows from operating activities:		
Net income	\$2,965,295	\$2,990,419
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,455,701	997,697
Stock-based compensation expense	835,585	707,389
Deferred income taxes	890,352	(247,801 )
Provision for bad debt reserve	272,723	-
Provision for inventory	592,241	168,593
Tax benefit from exercise of stock options	-	(27,349 )
Changes in operating assets and liabilities:		
Accounts receivable	(3,467,618 )	(2,563,772 )
Inventories	(1,499,923 )	(1,600,031 )
Prepaid expenses, other current and long-term assets	880,396	221,504
Long-term deposits and other	16,091	-
Accounts payable	3,050,687	777,956
Accrued expenses	(755,781 )	-
Deferred revenue	(2,076,468 )	(2,010,183 )
Income taxes payable	-	403,896
Other long-term liabilities	(104,073 )	108,648
Net cash provided by (used in) operating activities	4,055,208	(73,034 )
Cash flows from investing activities:		
Purchase of property and equipment, net	(1,817,716 )	(3,410,825 )
Reduction in purchase price of subsidiary	105,300	-
Net cash used in investing activities	(1,712,416 )	(3,410,825 )
Cash flows from financing activities:		
Principal payments on debt	(1,200,000 )	(1,200,000 )
Proceeds from exercise of stock options	197,243	3,150
Tax benefit from exercise of stock options	29,157	27,349
Net cash used in financing activities	(973,600 )	(1,169,501 )
Exchange rate impact on cash	(30,259 )	-
Increase (decrease) in cash and cash equivalents	1,338,934	(4,653,360 )
Cash and cash equivalents at beginning of period	24,426,990	43,193,655
Cash and cash equivalents at end of period	\$25,765,924	\$38,540,295

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



ANIKA THERAPEUTICS, INC.  
NOTES TO CONDENSED FINANCIAL STATEMENTS  
(Unaudited)

1. Nature of Business

Anika Therapeutics, Inc. (together with its subsidiaries, “Anika,” the “Company,” “we,” “us,” or “our”) develops, manufacture and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (“HA”), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

On December 30, 2009, Anika Therapeutics, Inc. entered into a Sale and Purchase Agreement (the “Purchase Agreement”) with Fidia Farmaceutici S.p.A. a privately held Italian corporation (“Fidia”), pursuant to which the Company acquired 100% of the issued and outstanding stock of Fidia Advanced Biopolymers S.r.l., a privately held Italian corporation (“FAB”), for a purchase price consisting of \$17.0 million in cash and 1,981,192 shares of the Company’s common stock.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with the U.S. Food and Drug Administration (“FDA”) government regulations and approval requirements as well as the ability to grow the Company’s business.

2. Basis of Presentation

The accompanying unaudited condensed financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) and in accordance with accounting principles generally accepted in the United States (“U.S.”). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. The year-end consolidated balance sheet is derived from our audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. In the opinion of management, these condensed financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the consolidated financial position of the Company as of September 30, 2010 and the results of its operations for the three and nine months ended September 30, 2010 and 2009 and cash flows for the nine months ended September 30, 2010 and 2009.

The accompanying unaudited condensed 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, 2009. There have been no changes in our significant accounting policies for the nine months ended September 30, 2010 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009. The results of operations for the three and nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010, or any future periods.

Management has reviewed and evaluated material subsequent events from the balance sheet date of September 30, 2010 through the financial statements issue date of November 9, 2010. All appropriate subsequent event disclosures, if any, have been made in these Notes to Condensed Consolidated Financial Statements.



3. Recent Accounting Pronouncements

In September 2009, the Emerging Issues Task Force (“EITF”) issued “Revenue Arrangements with Multiple Deliverables.” This issue addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, and how to allocate the consideration to each unit of accounting. This issue will supersede EITF 00-21 “Revenue Arrangements with Multiple Deliverables.” This issue eliminates the use of the residual value method for determining allocation of arrangement consideration, and allows the use of an entity's best estimate to determine the selling price if vendor specific objective evidence and third-party evidence can not be determined. This issue also requires additional disclosure to provide both qualitative and quantitative information regarding the significant judgments made in applying this issue. In addition, for each reporting period in the initial year of adoption, this issue requires disclosure of the amount of revenue recognized subject to the measurement requirements of this issue and the amount of revenue that would have been recognized if the related transactions were subject to the measurement requirements of EITF 00-21. It is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We believe the adoption of this new guidance will not have a material impact on our condensed consolidated financial statements.

In January 2010, the Financial Accounting Standards Board (“FASB”) issued “Fair Value Measurements and Disclosures - Improving Disclosures about Fair Value Measurements.” This statement requires some new disclosures and clarifies some existing disclosure requirements about fair value measurement. The amendments are effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. We believe the adoption of this new guidance will not have a material impact on our condensed consolidated financial statements.

In April 2010, the EITF issued “Revenue Recognition – Milestone Method.” This issue provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The new guidance recognizes the milestone method as an acceptable revenue recognition method for substantive milestones in research or development transactions. It is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We believe the adoption of this new guidance will not have a material impact on our condensed consolidated financial statements.

#### 4. Fair Value Measurements

We measure certain assets and liabilities such as fixed income investments at fair value based upon exit price, representing the amount that would be received on the sale of an asset or paid to transfer a liability, as the case may be, in an orderly transaction between market participants. As such, fair value may be based on assumptions that market participants would use in pricing an asset or liability. To increase the comparability of fair value measure, the following hierarchical levels of inputs to valuation methodologies are used:

Level 1 – Valuation is based upon quoted prices for identical instruments traded in active markets. Level 1 instruments include securities traded on active exchange markets, such as the New York Stock Exchange.

Level 2 – Valuation is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market.

Level 3 – Valuation is generated from model-based techniques that use significant assumptions not observable in the market. These unobservable assumptions reflect our own estimates of assumptions market participants would use in pricing the asset or liability.

The following table summarizes our assets measured and recorded at fair value on a recurring basis, by level, within the fair value hierarchy:

	September 30, 2010			Total
	Level 1	Level 2	Level 3	
Cash equivalents - money market accounts	\$20,236,659	\$-	\$-	\$20,236,659
	December 31, 2009			Total
	Level 1	Level 2	Level 3	
Cash equivalents - money market accounts	\$20,212,991	\$-	\$-	\$20,212,991



## 5. Stock-Based Compensation

The Company estimates the fair value of stock options and stock appreciation rights using the Black-Scholes valuation model. Fair value of restricted stock is measured by the grant-date price of the Company's shares. The fair value of each stock option and stock appreciation rights award during the three and nine months ended September 30, 2010 and 2009 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,			
	2010		2009	
Risk free interest rate	1.10	%	1.89	%
Expected volatility	62.08	%	61.03	%
Expected lives (years)	4		4	
Expected dividend yield	0.00	%	0.00	%
	Nine Months Ended September 30,			
	2010		2009	
			1.54%	
Risk free interest rate	1.79	%	-1.89	%
			59.35%	-
Expected volatility	62.08	%	61.03	%
Expected lives (years)	4		4	
Expected dividend yield	0.00	%	0.00	%

The Company recorded \$289,434 and \$835,585 of share-based compensation expense for the three and nine months ended September 30, 2010, respectively, for equity compensation awards. The Company recorded \$252,433 and \$707,389 of share-based compensation expense for the three and nine months ended September 30, 2009, respectively, for equity compensation awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the same employees.

### Stock Option Plan

The Company has reserved 2,350,000 shares of common stock for grant to employees, directors, consultants and advisors under the 2003 Plan. The Company issues new shares upon share option exercises from its authorized shares. Stock-based awards are granted with an exercise price equal to the market price of the Company's stock on the date of grant. The Company's stock-based awards contain service or performance conditions. Awards generally vest annually over 3 to 4 years. Awards have 10-year contractual terms.

## 6. Earnings Per Share

The Company reports earnings per share in accordance with Accounting Standards Codification 260, Earnings Per Share, formerly SFAS No. 128, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding and the number of dilutive potential common share equivalents during the period. Under the treasury stock method, unexercised "in-the-money" stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period.



Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Basic and diluted earnings per share for the three and nine months ended September 30, 2010 and 2009 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Basic earnings per share</b>				
Net income	\$ 1,184,264	\$ 1,511,925	\$ 2,965,295	\$ 2,990,419
Income allocated to participating securities	(2,200 )	(6,753 )	(5,288 )	(11,170 )
Income available to common stockholders	1,182,064	1,505,172	2,960,007	2,979,249
Basic weighted average common shares outstanding	12,633,405	11,385,679	12,615,705	11,379,128
Basic earnings per share	\$0.09	\$0.13	0.23	\$0.26
<b>Diluted earnings per share</b>				
Net income	\$ 1,184,264	\$ 1,511,925	\$ 2,965,295	\$ 2,990,419
Income allocated to participating securities	(2,042 )	(6,647 )	(4,910 )	(11,021 )
Income available to common stockholders	1,182,222	1,505,278	2,960,385	2,979,398
Weighted average common shares outstanding	12,633,405	11,385,679	12,615,705	11,379,128
Diluted potential common shares	989,198	190,228	983,181	156,593
Diluted weighted average common shares and potential common shares	13,622,603	11,575,907	13,598,886	11,535,721
Diluted earnings per share	\$0.09	\$0.13	\$0.22	\$0.26

In connection with the acquisition of FAB on December 30, 2009, the Company issued 1,981,192 shares of Anika common stock. As part of this transaction, 800,000 of these shares were to be held in escrow for one year. These 800,000 shares are included in the diluted potential common shares but are excluded from the basic earnings per share calculation.

Equity awards of 1,152,913 and 1,108,095 shares were outstanding for the three and nine months ended September 30, 2010, respectively, but not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive. Equity awards of 854,102 and 1,005,880 shares were outstanding for the three and nine months ended September 30, 2009, respectively, but not included in the computation of diluted earnings per share because the awards' impact on earnings per share was anti-dilutive.

## 7. Inventories

Inventories consist of the following:

	September 30, 2010	December 31, 2009
Raw materials	\$ 2,938,447	\$ 2,535,496
Work-in-process	2,567,238	3,188,241
Finished goods	3,889,396	2,823,602
Total	\$ 9,395,081	\$ 8,547,339

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

## 8. Intangible Assets and Goodwill

On December 30, 2009, in connection with the acquisition of FAB, the Company acquired various intangible assets and goodwill. The Company evaluated the various intangibles and related cash flows from these intangible assets, as well as the useful lives and amortization methods related to these intangibles. The in-process research and development (“IPR&D”) intangible assets initially have indefinite lives and will be reviewed periodically to assess the project status, valuation, and disposition including write-off for abandoned projects. Until such determination, they are not amortized.

The Company periodically reviews its long-lived assets for impairment. The Company initiates a review for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of the assets are no longer appropriate, such as a significant reduction in cash flows associated with the assets. Each impairment test will be based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value.

Intangible assets as of September 30, 2010 and December 31, 2009 consist of the following:

	September 30, 2010			December 31, 2009		
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$15,700,000	\$(791,671 )	\$ (745,416 )	\$14,162,912	\$15,700,000	15
In-process research & development	11,300,000	(569,802 )	-	10,730,198	11,300,000	Indefinite
Distributor relationships	4,700,000	(236,997 )	(669,450 )	3,793,552	4,700,000	5
Patents	1,000,000	(50,425 )	(44,511 )	905,064	1,000,000	16
Eleveess trade name	1,000,000	-	(216,562 )	783,438	877,451	9
Total	\$33,700,000	\$(1,648,895)	\$ (1,675,940 )	\$30,375,165	\$33,577,451	

The aggregate amortization expense related to intangible assets was \$492,512 and \$1,506,584 for the three and nine months ended September 30, 2010, respectively. The estimated annual amortization expense for the next five years is expected to be approximately \$2.1 million plus the impact of IPR&D once development of this technology is completed.

The change in the Goodwill balance related to the FAB acquisition from December 31, 2009 is due to the cumulative currency translation adjustment as a result of the foreign exchange rate fluctuation during the nine months ended September 30, 2010, as well as the adjustments discussed in the following paragraph.

During the second quarter of fiscal 2010, the Company substantially completed the purchase price allocation for the fiscal year 2009 acquisition of FAB. Some of the amounts previously estimated have changed during the measurement period. The changes in estimates of acquired assets and assumed liabilities at the acquisition date include an increase in inventory of approximately \$106,000, an increase in net other assets of approximately \$18,000 and a decrease in deferred tax liabilities of approximately \$39,000. As a result of these changes, there is a net decrease in goodwill of approximately \$164,000. The measurement period adjustments represent updates made to the preliminary purchase price allocation based on revisions to valuation estimates in the interim period subsequent to the acquisition and initial accounting date. These measurement period adjustments have been retrospectively applied to the balance sheet at December 31, 2009. There was no significant impact to the Company's Consolidated Statement of Operations for any periods prior to the interim period ended June 30, 2010.

## 9. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2010	December 31, 2009
Payroll and benefits	\$ 1,913,904	\$ 2,137,067
Professional fees	362,044	1,470,007



Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

Clinical trial costs	72,000	129,509
FAB research grants	1,543,101	1,625,044
Other	973,776	454,543
Total	\$ 4,864,825	\$ 5,816,170

9

---

## 10. Commitments and Contingencies

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

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The Complaint alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents.

Artes Medical, Inc. ("Artes"), the former U.S. distributor of HYDRELLE, filed a liquidating bankruptcy case under Chapter 7 of the United States Bankruptcy Code. Artes' Trustee in Bankruptcy asked the Company to pay \$359,768 to the Trustee, representing the total amount of three payments received by the Company from Artes within the 90 days prior to the filing of Artes' liquidating bankruptcy. The Trustee asserts that the payments are recoverable as preferences under the Bankruptcy Code.

The Company believes that the payments it received either do not meet the legal requirements of avoidable preferences or are subject to one or more exceptions to the Trustee's powers to recover preferences and has recently so advised the Trustee. Management has assessed and determined that contingent losses related to this matter are remote. Therefore, pursuant to ASC Topic 450, an accrual has not been recorded for this loss contingency.

## 11. Long-term Debt

On January 31, 2008, the Company entered into an unsecured Credit Agreement with Bank of America. As of September 30, 2010, the Company had an outstanding debt balance of \$13,200,000, at an interest rate of 1.54%. The interest payable on our debt is determined, at the Company's option, based on LIBOR plus 1.25%, or the lender's prime rate.

Accounting Standards Codification 825, Financial Instruments ("ASC 825"), requires disclosure about the fair value of financial instruments in interim as well as in annual financial statements. The carrying value of our debt instrument was \$13,200,000 and \$14,400,000 at September 30, 2010 and December 31, 2009, respectively. The estimated fair value of our debt instrument was approximately \$12,600,000 and \$13,800,000 at September 30, 2010 and December 31, 2009, respectively, using market observable inputs and interest rate measurements.

## 12. Income Taxes

Income tax expense was \$853,485 and \$460,232 for the three months ended September 30, 2010 and 2009, respectively, and \$1,945,086 and \$948,899 for the nine months ended September 30, 2010 and 2009,

respectively. The effective tax rates were 41.9% and 23.3% for the three months ended September 30, 2010 and 2009, respectively, and 39.6% and 24.1% for the nine months ended September 30, 2010 and 2009, respectively.

The increase in the effective tax rates were primarily due to a lower investment tax credit in 2010 compared to 2009, the expiration of the U.S. federal research and development tax credit during 2010, and FAB's losses in Italy at a comparatively lower statutory tax rate than the U.S.

The Internal Revenue Service recently commenced an audit of our 2008 tax return, but the outcome and financial impact of this audit cannot be estimated at this time. The Company files income tax returns in the U.S. on a federal basis, in certain U.S. states, and in Italy. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. Our U.S. federal income tax returns for the years 2006 to 2009, our state income tax returns for 2008 and 2009, and our Italian income tax returns for 2009 all remain subject to examination.

## 13. Pro-Forma Financial Information

The FAB operating results for the third quarter and nine months of 2009 are not included in the financial results of the Company for that period as the acquisition occurred on December 30, 2009. The following unaudited pro-forma summary presents consolidated information of the Company as if FAB had been acquired as of January 1, 2009, compared with the Company's actual results for the nine months ended September 30, 2010:

	Nine Months Ended September 30,	
	2010	2009
	Consolidated (unaudited)	Pro forma (unaudited)
Total revenue	\$ 40,835,101	\$ 36,381,000
Net income	\$ 2,965,295	\$ (1,866,000 )
Diluted net income per share:		
Net income	\$ 0.22	\$ (0.14 )
Diluted weighted average common shares outstanding	13,598,886	13,517,000

## 14. Related Party

In connection with the acquisition of FAB by Anika on December 30, 2009, Fidia acquired ownership of 1,981,192 shares of the Company's common stock, or approximately 14.8% of the outstanding shares of the Company as of December 30, 2009. As of September 30, 2010, Fidia owns approximately 14.7% of the outstanding shares of the Company.

As part of the acquisition, the Company, primarily through FAB, entered into a series of operating agreements with Fidia as follows:

Agreement Type	Description	Term in Years
Lease	Rent of space in Abano Terme, Italy	Six
Finished goods supply	Manufacture and supply of goods	Three
Raw material supply	Hyaluronic acid powder	Five
Services	Finance, administrative, security	One to Six
Accounts receivable management	Collection of trade receivables outstanding as of December 30, 2009.	Two
Marketing and Promotion	Promote FAB products in Italy through Fidia sales force	Three

Historically, FAB has relied on Fidia, its former parent company, for several functional activities. In connection with the purchase of FAB, the Company has negotiated a lease for approximately 26,000 square feet of office, laboratory and warehouse space in Abano Terme, Italy, and a finished goods supply agreement. In addition, accounting and purchasing will be performed by Fidia on behalf of FAB during 2010 under a services agreement. Finally, Fidia has agreed to promote FAB's products in Italy through its existing 140 person sales force. At September 30, 2010, FAB had a net payable to Fidia for past products and services of \$5.3 million.



## 15. Segment, Customer and Geographic Information

The Company has one reportable operating segment, the results of which are disclosed in the accompanying condensed consolidated financial statements.

Product revenue by product group is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Orthobiologics	\$ 7,675,342	\$ 6,136,101	\$ 22,321,859	\$ 16,854,428
Dermal	318,833	623,358	2,402,852	761,532
Ophthalmic surgery	3,332,883	2,705,897	8,768,851	7,832,072
Surgical	1,187,378	37,065	2,974,869	95,290
Veterinary	664,963	584,709	2,073,947	1,833,644
	\$ 13,179,399	\$ 10,087,130	\$ 38,542,378	\$ 27,376,966

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010		2009		2010		2009	
Depuy Mitek	43	%	44	%	43	%	44	%
Bausch & Lomb Incorporated	24	%	25	%	21	%	27	%
Boehringer Ingelheim								
Vetmedica	5	%	6	%	5	%	7	%
Medtronic	5	%	0	%	4	%	0	%
Biomeks	4	%	6	%	4	%	6	%
	81	%	81	%	77	%	84	%

As of September 30, 2010, five customers represented 63% of the Company's accounts receivable balance, and as of December 31, 2009, five customers represented 53% of the Company's accounts receivable balance.

Product revenue by geographic location in total and as a percentage of total product revenue, for the three and nine months ended September 30, 2010 and 2009 are as follows:

Geographic Location:	Three Months Ended September 30,		Three Months Ended September 30,	
	2010	Percentage of Revenue	2009	Percentage of Revenue
United States	\$ 9,212,832	70 %	\$ 7,317,404	73 %
Europe	2,850,595	22 %	1,923,502	19 %
Other	1,115,972	8 %	846,224	8 %
Total	\$ 13,179,399	100 %	\$ 10,087,130	100 %

  

Nine Months Ended September 30,	
2010	2009

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-Q

	Revenue	Percentage of Revenue		Revenue	Percentage of Revenue
Geographic Location:					
United States	\$ 26,488,673	69 %	\$	19,914,630	73 %
Europe	9,024,021	23 %		4,728,911	17 %
Other	3,029,684	8 %		2,733,425	10 %
Total	\$ 38,542,378	100 %	\$	27,376,966	100 %

## ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF 2. 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 revenue, including geographic expansions, possible retroactive price adjustments, and expectations of unit volumes or other offsets to price reductions;
- our manufacturing capacity and efficiency gains and work-in-process manufacturing operations;
- the timing, scope and rate of patient enrollment for clinical trials;
- the development of possible new products;
- our ability to achieve or maintain compliance with laws and regulations;
- the timing of and/or receipt of the Food and Drug Administration ("FDA"), foreign or other regulatory approvals and/or reimbursement approvals of current, new or potential products, and any limitations on such approvals;
- our intention to seek patent protection for our products and processes, and protect our intellectual property;
- our ability to effectively compete against current and future competitors;
- negotiations with potential and existing partners, including our performance under any of our existing and future distribution or supply agreements or our expectations with respect to sales and sales threshold milestones pursuant to such agreements;
- the level of our revenue or sales in particular geographic areas and/or for particular products, and the market share for any of our products;
- our current strategy, including our corporate objectives and research and development and collaboration opportunities;
- our and Bausch & Lomb's (B&L) performance under the existing supply agreement for certain of our ophthalmic viscoelastic products, our expectations that we will no longer remain the exclusive global supplier for AMVISC and AMVISC Plus to Bausch & Lomb beyond the December 31, 2010 expiration date, and our expectations regarding future revenue from ophthalmic products after 2010;
- Our expectations regarding entry into a limited term extension of the supply agreement with B&L, if at all;
- our expectations regarding our joint health products, including expectations regarding new products, expanded uses of existing products, new distributors, product sales and revenue growth;
- our intention to increase market share for joint health products in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;
-



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

- our expectations regarding HYVISC sales;
- our ability to identify a new distribution partner for HYDRELLE in the U.S. and our ability to directly distribute HYDRELLE in the interim period and the impact they may have on future sales of this product;
- our ability to license our aesthetics product to new distribution partners outside of the United States; our ability, and the ability of our distribution partners, to market our aesthetic dermatology product; and our expectations regarding the distribution and sales of our ELEVESS product and the timing thereof;

- our expectations regarding product gross margin;
- our expectations regarding our U.S. MONOVISC trials and the timing of the related premarket approval (“PMA”) from the FDA, including the likelihood of our obtaining such approval and/or the anticipated timing thereof;
- our expectations regarding our existing aesthetics product’s line extensions;
- our expectation for increases in operating expenses, including research and development and selling, general and administrative expenses;
- the rate at which we use cash, the amounts used and generated by operations, and our expectation regarding the adequacy of such cash;
- our expectation for capital expenditures spending and decline in interest income;
- possible negotiations or re-negotiations with existing or new distribution or collaboration partners;
- our expectations regarding our existing manufacturing facility and the Bedford, MA facility;
- our expectations related to costs, including financing costs, to build-out and occupy the new Bedford, MA facility, the timing of construction, and our ability to obtain FDA licensure for the facility;
- our expectation regarding the impact of our Bedford, MA facility and annual depreciation expense;
- our abilities to comply with debt covenants;
- our ability to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and other sources, to the extent our current sources of funds are insufficient;
- our ability to successfully integrate Fidia Advanced Biopolymers (“FAB”), our recently acquired subsidiary, into the Company and manage the operation from one with losses, into a company generating profits;
- our ability to integrate our research and development activity with those of FAB and effectively prioritize the many projects underway at both companies;
- our ability to obtain U.S. approval for the orthopedic and other products of FAB, including the timing and potential success of such efforts, and to expand sales of these products in the U.S., including the impact such efforts may have on our revenue;
- our ability to directly commercialize MONOVISC, HYDRELLE, and the FAB products directly to customers, and the potential increase in expenses associated therewith; and
- our ability to successfully defend the Company against lawsuits and claims, including the Genzyme lawsuit, and the uncertain financial impact such lawsuits and claims and related defense costs may have on the Company.

Furthermore, additional statements identified by words such as “will,” “likely,” “may,” “believe,” “expect,” “anticipate,” “i seek,” “designed,” “develop,” “would,” “future,” “can,” “could,” and other expressions that are predictions of or indicate

events and trends and which do not relate to historical matters, also identify forward-looking statements. You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled “Item 1A. Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2009. These risks, uncertainties and other factors may cause our actual results, performance or achievement to be materially different from anticipated future results, performance or achievement, expressed or implied by the forward-looking statements. These forward-looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences, including those factors discussed herein and in the “Management’s Discussions and Analysis of Financial Condition and Results of Operations” section of this Quarterly Report on Form 10-Q, as well as the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2009 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors of new information, future events or other changes.

## Management Overview

Anika Therapeutics, Inc. (together with its subsidiaries, “Anika,” the “Company,” “we,” “us,” or “our”) develops, manufactures and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (“HA”), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

On December 30, 2009, Anika entered into a Sale and Purchase Agreement (the “Purchase Agreement”) with Fidia Farmaceutici S.p.A., a privately held Italian corporation (“Fidia”), pursuant to which the Company acquired 100% of the issued and outstanding stock of Fidia Advanced Biopolymers S.r.l., a privately held Italian corporation (“FAB”), for a purchase price consisting of \$17.0 million in cash and 1,981,192 shares of the Company’s common stock valued at \$16.8 million based on the closing stock price of \$8.49 per share on December 30, 2009.

FAB has over 20 products currently commercialized, primarily in Europe. These products are all made from HA, and are based on two technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Both technologies are protected by an extensive portfolio of patents. With the acquisition of FAB, the Company is offering therapeutic products in the following areas:

	Anika	FAB
Orthobiologics	X	X
Dermal		
Advanced wound care		X
Aesthetic dermatology	X	
Ophthalmic surgery	X	
Surgical		
Anti-adhesion	X	X
Ear, nose and throat care (“ENT”)		X
Veterinary	X	

## Orthobiologics

Anika’s orthobiologics business contributed 58% to our product revenue in the nine months ended September 30, 2010. This includes FAB’s products which added \$1,238,235 to orthobiologics revenue during the nine months ended September 30, 2010, but were not included in revenue during the same period last year. Within this product group, our joint health products include ORTHOVISC, ORTHOVISC mini, and MONOVISC. ORTHOVISC is available in the U.S., Canada, and some international markets for the treatment of osteoarthritis of the knee, and in Europe for the treatment of osteoarthritis in all joints. ORTHOVISC mini is available in Europe and is designed for the treatment of osteoarthritis in small joints. MONOVISC is our single injection osteoarthritis treatment indicated for all joints in Europe, and for the knee in Turkey and Canada. In December 2009, we submitted the final module of our premarket approval (“PMA”) application to the FDA seeking approval to market MONOVISC in the U.S. We held a meeting with the FDA regarding our PMA, during which they requested additional statistical data. Our response to the FDA’s questions was submitted in October 2010. This lengthens our approval process, and likely will delay our launch of MONOVISC in the U.S. market into 2011. See also “Litigation and Other Legal Matters” in this Form 10-Q regarding Genzyme Corporation’s complaint against Anika relating to MONOVISC.

Anika has marketed ORTHOVISC, our product for the treatment of osteoarthritis of the knee, internationally since 1996 through various distribution agreements. International sales of ORTHOVISC contributed 9% of product revenue for the nine months ended September 30, 2010. Our strategy is to continue to add new products, to expand the indications for usage of these products, and to add additional countries to our distribution network. The joint health area has been the fastest growing area for the Company, growing from 39% of our product revenue in 2005 to 58% of our product revenue in the first nine months ended September 30, 2010. We continue to seek new distribution partnerships around the world and we expect total joint health product sales to increase in 2010 compared to 2009.

With the acquisition of FAB, we now offer several additional products within the orthobiological product group, used in connection with orthopedic regenerative medicine. The products currently available in Europe include Hyalograft C Autograft for cartilage regeneration; Hyalofast, a biodegradable support for human bone marrow mesenchymal stem cells; Hyalonect, a woven gauze used as a graft wrap; and Hyaloss, HYAFF fibers used to mix blood/bone grafts to form a paste for bone regeneration. Through FAB we also offer Hyaloglide, an ACP gel used in tenolysis treatment, but with potential for flexor tendon adhesion prevention, and in the shoulder for adhesive capsulitis. FAB's products are commercialized directly in Italy, and distributed internationally through a network of distributors, primarily in Europe, the Middle East, Argentina, and Korea. While not currently approved in the U.S., Anika believes that the U.S. market offers excellent expansion potential to increase revenue from these FAB orthopedic products.

## Dermal Products

Our dermal products consist of our aesthetic dermal fillers and FAB's advanced wound care products, a field new to the Company. Altogether, our dermal products contributed 6% of our product revenue for the first nine months ended September 30, 2010. FAB offers nine products for treatment of skin wounds ranging from burns to severe chronic wounds, including diabetic ulcers. The products cover a variety of wound treatment solutions, including debridement agents, advanced therapies and skin substitutes. FAB's leading products include Hyalograft 3D Autograft, for the regeneration of skin; and Hyalomatrix and Hyalofill, for the treatment of difficult to heal wounds, including burns and ulcers. Hyalomatrix is the only product on the market not contra-indicated for 3rd degree burns. FAB's products are commercialized directly in Italy, and sold through a network of distributors, primarily in Europe, the Middle East, Argentina, and Korea. Several of the products are also approved for sale in the U.S., and the Company is currently exploring distribution opportunities. There have been no U.S. sales of these products in 2010. Sales of our advanced wound care products were \$2,120,633 for the nine months ended September 30, 2010.

Our aesthetic dermatology business is designed as a family of products for facial wrinkles and scar remediation, and is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. Our initial aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA, and is approved in Europe, Canada, the U.S. and certain countries in South America. Internationally, this product is marketed under the ELEVESS name. We continue to focus on the development and expansion of the product in additional countries and added distributors in Poland, Egypt, and Korea late in 2009. This product has been marketed in the U.S. under the name of HYDRELLE. Coapt Systems, Inc. ("Coapt") began selling HYDRELLE in the third quarter of 2009. In July 2010, Coapt made a general assignment for the benefit of creditors and an Assignee began the liquidation of Coapt's assets. The Company's Distribution Agreement with Coapt has been terminated. The Company plans to directly distribute HYDRELLE in the interim while it seeks a new U.S. distributor. Sales for our aesthetic dermatology business were \$282,219 for the nine months ended September 30, 2010.

## Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the nine months ended September 30, 2010, sales of ophthalmic products contributed 23% of our product revenue. Sales to Bausch & Lomb accounted for 94% of ophthalmic sales for the nine months ended September 30, 2010, and contributed 21% of product revenue.

## Surgical

INCERT, approved for sale in Europe and Turkey, is a chemically modified, cross-linked HA, for the prevention of post-surgical adhesions. With the acquisition of FAB, we now also offer Hyalobarrier and Hyalobarrier Endo, two clinically proven post operative adhesion barriers approved for abdominal indications. The products are currently commercialized in Europe, the Middle East and certain Asian countries through a distribution network. Sales of our anti-adhesion products were \$954,493 for the nine months ended September 30, 2010, and represent approximately 2% of product revenue.

FAB offers a variety of products used in connection with the treatment of ear, nose and throat ("ENT") disorders. The lead product is Merogel, a thick, viscous hydrogel composed of cross-linked hyaluronic acid—a biocompatible agent that creates a moist wound-healing environment. FAB is partnered with Medtronic for worldwide distribution of ENT products outside of Italy. Sales of ENT products were \$2,020,376 for the nine months ended September 30, 2010, or approximately 5% of product revenue.

Veterinary Business

Sales of HYVISC, our veterinary product for the treatment of equine osteoarthritis were \$2,073,947 and contributed 5% to product revenue for the nine months ended September 30, 2010. We continue to look at other veterinary applications and opportunities to expand geographic territories.

## Research and Development

Products in development include MONOVISC for U.S. marketing approval, and additional next generation joint health related products. MONOVISC is our next generation osteoarthritis product and is a single-injection treatment that uses a non-animal source HA. It is our first osteoarthritis product based on our proprietary crosslinked HA-technology. We received European CE Mark approval for the MONOVISC product in October 2007 and began sales in Europe during the second quarter of 2008, following a small, post marketing clinical study. In the U.S., we filed an investigational device exemption application, or an IDE application, with the FDA, and completed the clinical segment of the U.S. MONOVISC pivotal trial in June 2009 and a follow-on retreatment study in September 2009. We completed a PMA application filing with the FDA in December 2009 which is currently under review. We held a meeting with the FDA regarding our PMA, during which they requested additional statistical data. Our response to the FDA's questions was submitted in October 2010. This lengthens our approval process, and likely will delay our launch of MONOVISC in the U.S. market into 2011. See also "Litigation and Other Legal Matters" in this Form 10-Q regarding Genzyme Corporation's complaint against Anika relating to MONOVISC. Our second single-injection osteoarthritis product is CINGAL, which is based on the same technology platform used in MONOVISC, with an added active therapeutic molecule to provide broad pain relief for a long period of time.

Our new subsidiary, FAB, has a number of research and development projects underway. Key projects include obtaining FDA approval to market FAB's suite of orthopedic products in the U.S. These products consist of Hyalofast®, Hyaloglide®, and Hyalonect®. We filed 510k applications with the FDA during the fourth quarter of 2010 to gain marketing approval for these products. A key objective for 2010 has been to integrate our research and development activities, and to prioritize the many projects currently underway at both companies.

## FDA Warning Letter

In July 2008, we received a Warning Letter (the "Warning Letter") from the FDA in response to an earlier FDA Form 483 Notice of Observations issued to us following an inspection at our current manufacturing facility in Woburn, Massachusetts. The Company submitted corrective action plans, which have been accepted by the FDA and resulted in the clearance of the Warning Letter.

## Contracts

Anika has been a contract manufacturer for Bausch & Lomb ("B&L") for over 20 years, and the current Supply Agreement with B&L expires on December 31, 2010. The parties are negotiating a limited term extension, which is expected to generate significantly less revenue in 2011 for Anika, as B&L transitions to a low cost supplier recently affiliated with the ownership of B&L. The Company is still assessing the impact of this contract termination on future results, but believes there are additional ophthalmic opportunities available to partially offset the financial impact.

## Litigation and Other Legal Matters

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The Complaint alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents.



Artes Medical, Inc. (“Artes”), the former U.S. distributor of HYDRELLE, filed a liquidating bankruptcy case under Chapter 7 of the United States Bankruptcy Code. Artes’ Trustee in Bankruptcy asked the Company to pay \$359,768 to the Trustee, representing the total amount of three payments received by the Company from Artes within the 90 days prior to the filing of Artes' liquidating bankruptcy. The Trustee asserts that the payments are recoverable as preferences under the Bankruptcy Code.

The Company believes that the payments it received either do not meet the legal requirements of avoidable preferences or are subject to one or more exceptions to the Trustee's powers to recover preferences and has recently so advised the Trustee. Management has assessed and determined that contingent losses related to this matter are remote. Therefore, pursuant to ASC Topic 450, an accrual has not been recorded for this loss contingency.

Coapt Systems, Inc., the Company's former distributor for its HYDRELLE product, made a general assignment for the benefit of creditors and an Assignee began the liquidation of Coapt's assets. The Company's Distribution Agreement with Coapt has been terminated and the Company plans to directly distribute HYDRELLE domestically in the interim while it determines its worldwide strategy for the franchise. For the period ended June 30, 2010, the Company increased its reserves by approximately \$270,000 for outstanding Coapt receivables.

## Results of Operations

## Product Revenue

Product revenue for the quarter ended September 30, 2010 was \$13,179,399, an increase of 31%, compared to \$10,087,130 for the quarter ended September 30, 2009. Product revenue for the nine months ended September 30, 2010 was \$38,542,378, an increase of 41%, compared to \$27,376,966 for the nine months ended September 30, 2009. Excluding the contributions of FAB, Anika's product revenue grew 14% and 18% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009.

	Three Months Ended September 30,		Increase (Decrease)		
	2010	2009	\$	%	
Orthobiologics	\$ 7,675,342	6,136,101	\$ 1,539,241	25	%
Dermal	318,833	623,358	(304,525)	NM	
Ophthalmic surgery	3,332,883	2,705,897	626,986	23	%
Surgical	1,187,378	37,065	1,150,313	NM	
Veterinary	664,963	584,709	80,254	14	%
	\$ 13,179,399	\$ 10,087,130	\$ 3,092,269	31	%

NM = Not Meaningful

	Nine Months Ended September 30,		Increase (Decrease)		
	2010	2009	\$	%	
Orthobiologics	\$ 22,321,859	\$ 16,854,428	\$ 5,467,431	32	%
Dermal	2,402,852	761,532	1,641,320	NM	
Ophthalmic surgery	8,768,851	7,832,072	936,779	12	%
Surgical	2,974,869	95,290	2,879,579	NM	
Veterinary	2,073,947	1,833,644	240,303	13	%
	\$ 38,542,378	\$ 27,376,966	\$ 11,165,412	41	%

NM = Not Meaningful

Historically, our joint health products, which are a part of our orthobiologics group, consist of ORTHOVISC, ORTHOVISC mini and MONOVISC, the latter two of which are currently only available outside the U.S. Revenue from these joint health products increased 20% and 25% to \$7,344,831 and \$21,083,624 during the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009. The improvement in joint health product revenue for both periods was due to increases in domestic ORTHOVISC revenue, as well as increased sales of MONOVISC in Europe and Turkey in 2010. Our U.S. joint health product revenue for the three and nine months ended September 30, 2010 totaled \$5,694,247 and \$16,364,849, compared to \$4,388,677 and \$12,148,161, respectively, during the same periods in 2009, representing an increase of 30% and 35% for the respective periods. This increase reflects DePuy Mitek's continued market penetration in the U.S. International joint health product revenue for the nine months ended September 30, 2010 were \$4,718,775 versus \$4,706,267 during the same period in 2009. The flat international revenue was primarily due to weak European economies. We expect joint health product revenue to increase in 2010 compared to 2009, both domestically and internationally.

In addition to our historic joint health products, FAB's orthopedic products currently available include Hyalograft C Autograft, Hyalofast, Hyalonect, Hyaloss, and Hyaloglide. These products are commercialized directly in Italy, and through a network of distributors, primarily in Europe, the Middle East, Argentina, and Korea. Revenue from orthopedic products were \$330,511 and \$1,238,235 for the three and nine-month periods ended September 30, 2010,

respectively, or approximately 3% of product revenue for both periods. FAB's orthopedic revenue was not included in the same period in 2009.

Anika's advanced wound care products, through its FAB subsidiary, consist of nine products for the treatment of skin wounds ranging from burns to diabetic ulcers. Leading products include Hyalomatrix 3D and Hyalomatrix. Sales of our advanced wound care products were \$288,852 and \$2,126,197, respectively, for the three and nine months ended September 30, 2010. Advanced wound care revenue was not included in the same period in 2009.

Aesthetic dermatology revenue was \$35,545 and \$282,219 for the three and nine months ended September 30, 2010, respectively, versus \$623,358 and \$761,532 for the same periods in 2009. In July 2010, our former U.S. distributor, Coapt, filed for protection from creditors and we terminated our agreement with them. Aesthetic revenue during the first half of 2009 was primarily a result of our direct marketing efforts in the U.S. We added several additional international distributors in the second half of 2009 and after a brief disruption in supply, resumed shipping ELEVESS to Europe in the third quarter of 2010. Certain Asian and Middle East markets require FDA approved product, and await shipments pending FDA approval of our Bedford, MA facility. We continue to seek additional marketing and distribution partners to commercialize our aesthetic products outside the U.S. The aesthetics' market is crowded with many large companies, and our sales expectations in this area are modest.

Ophthalmic products sales increased 23% to \$3,332,883 in the third quarter of 2010 as compared to \$2,705,897 in the same period in 2009. For the first nine months of 2010, ophthalmic sales were \$8,768,851, an increase of 12% over the same period of 2009. The increase was primarily attributable to order timing and inventory management by our partners.

Sales of our surgical products were \$1,187,378 and \$2,974,869 for the three and nine months ended September 30, 2010. This category consists of FAB's anti-adhesion and ENT products acquired in December 2009. Our anti-adhesion products include INCERT, Hyalobarrier and Hyalobarrier Endo. Our leading ear, nose and throat care product is Merogel. FAB is partnered with Medtronic for worldwide distribution (except for Italy) of its ENT products.

Veterinary revenue from HYVISC was \$664,963 and \$2,073,947 for the three and nine months ended September 30, 2010, a 14% and 13% increase as compared to the same periods in 2009. We believe the increases for both periods were primarily due to order timing by our distribution partner, Boehringer Ingelheim Vetmedica. We expect HYVISC revenue to increase slightly in 2010 compared to 2009.

#### Licensing, milestone and contract revenue

Licensing, milestone and contract revenue for the three and nine months ended September 30, 2010 was \$689,815 and \$2,292,723, respectively, compared to \$705,634 and \$2,139,798 during the same periods in 2009. The nine month increase was due to licensing and grant revenue from our FAB subsidiary, partially offset by a decrease in maintenance and contract revenue from Anika. Licensing and milestone revenue includes the ratable recognition of the \$27,000,000 in up-front and milestone payments related to the U.S. distribution agreement with Depuy Mitek received in 2004. These amounts are being recognized in income over the ten-year expected life of the agreement, or \$2,700,000 per year.

#### Product gross profit and margin

Product gross profit for the three and nine months ended September 30, 2010 were \$7,070,897 and \$21,418,448, or 54% and 56% of product revenue, respectively. This compares with \$6,535,756 and \$17,319,766, or 65% and 63% of product revenue, for the three and nine months ended September 30, 2009. The decrease in product gross profit and margin was primarily due to the impact of FAB, which currently operates at a lower volume and outsources most manufacturing to its former parent company, Fidia. In addition, the Company has increased its reserves by \$295,000 for inventory related matters during the first nine months of 2010. The Company plans to transfer a significant portion of the FAB product manufacturing to its location in Bedford, MA over the next two years. Looking forward, we expect a similar decline in gross margin in the U.S. in 2010 compared with 2009 as we transition operations from our Woburn, MA facility to our Bedford, MA facility. The transition will take place by product line and result in manufacturing activities occurring in both facilities for a significant portion of the year. Commencing in 2011, the Bedford, MA facility is expected to add in excess of \$2.2 million to annual depreciation expense once completely on-line.

## Research and development

Research and development expenses for the three and nine months ended September 30, 2010 were \$1,774,623 and \$5,486,920, respectively, or 13% of total revenue for both periods. This compared with \$2,382,146 and \$6,862,683, or 22% and 23% of total revenue, for both the three and nine months ended September 30, 2009. The decrease in research and development expenses was primarily due to the higher costs incurred in 2009 in connection with the Company's U.S.-based clinical trials for MONOVISC, and the post-marketing aesthetic dermatology "people of color" study during the three and nine months ended September 30, 2009. The MONOVISC clinical trial was completed in late 2009. This decrease was partially offset by the R&D costs incurred at our FAB subsidiary. Research and development during the nine months ended September 30, 2010 was primarily for manufacturing validation activities at our Bedford facility, as well as other continuing new product development projects in Italy and the U.S. We expect research and development expenses will increase significantly in the future with the addition of FAB's pipeline of new products.

### Selling, general and administrative

Selling, general and administrative expenses for the three and nine months ended September 30, 2010 were \$3,908,452 and \$13,164,775, respectively, or 28% and 32% of total revenue. This compared with \$2,842,991 and \$8,613,525, or 26% and 29% of total revenue, respectively, for the three and nine months ended September 30, 2009. The increase was primarily due to the addition of FAB to the Company, FAB integration costs, as well as costs related to the development of MONOVISC marketing materials and reimbursement strategy consulting. In addition, the Company increased its reserves in the second quarter by approximately \$270,000 for outstanding Coapt receivables due to Coapt's bankruptcy declaration. We expect general and administrative expenses for the fourth quarter of 2010 will compare with the third quarter's level, but that selling expenses may significantly increase as we prepare for the direct commercialization of MONOVISC in the U.S. Future general and administrative expenses could also be impacted by the Genzyme lawsuit and the potential for significant defense costs.

### Interest income (expense), net

Net interest expense was \$39,888 and \$149,095, respectively, for the three and nine months ended September 30, 2010. Interest expense incurred was capitalized during the construction/validation stages prior to July 1, 2009, and is the primary reason for the increased expense in 2010 versus 2009.

### Income taxes

Provisions for income taxes were \$1,945,086 and \$948,899 for the nine months ended September 30, 2010 and 2009, respectively, based on effective tax rates of 39.6% and 24.1% for the respective periods. The increase in the effective tax rate in 2010 is primarily due to a lower investment tax credit anticipated for 2010 compared to 2009, as well as the expiration of the U.S. federal research and development tax credit in 2010, and FAB's losses in Italy at a comparatively lower statutory tax rate than the U.S.

The Internal Revenue Service recently commenced an audit of our 2008 tax return, but the outcome and financial impact of this audit cannot be estimated at this time. The Company files income tax returns in the U.S. on a federal basis and in certain U.S. states and in Italy. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. Our U.S. federal income tax returns for the years 2006 to 2009, our state income tax returns for 2008 and 2009, and our Italian income tax returns for 2009 all remain subject to examination.

### Liquidity and Capital Resources

We require cash to fund our operating expenses and capital expenditures. We expect that our requirements for cash to fund operations will increase as the scope of our operations expands. Prior to 2008, we funded our cash requirements from operations as well as from existing cash and investments on hand. In 2008, we borrowed \$16.0 million from Bank of America to partially fund our Bedford, Massachusetts facility capital project, and have spent approximately \$34.0 million to date on this project to expand our operations and capabilities. In addition, in 2009 we spent \$16.2 million in cash in connection with the FAB acquisition. Cash and cash equivalents totaled \$25.8 million compared to \$24.4 million, and working capital totaled \$35.8 million and \$33.4 million, at September 30, 2010 and December 31, 2009, respectively. The Company believes it has adequate financial resources to support its business for the foreseeable future.

Cash provided by operating activities was \$4,055,208 for the nine months ended September 30, 2010, compared with cash used in operating activities of \$73,034 for the nine months ended September 30, 2009. This increase in cash

provided by operations was primarily due to an increase in depreciation and amortization expense, deferred income taxes, and receivable and inventory reserves, partially offset by an increase in net working capital requirements of approximately \$1,388,000.

Cash used in investing activities was \$1,712,416 for the nine months ended September 30, 2010, compared to \$3,410,825 for the nine months ended September 30, 2009. The decrease is due to lower expenditures related to our Bedford, MA facility project as it nears completion. We expect our capital expenditures in 2010 to be lower than 2009 as the new facility capital project winds down. As noted above, the Bedford, MA facility capital project cost is approximately \$34.0 million (including interior construction, equipment, furniture and fixtures). Construction commenced in May 2007 and validation of the facility is expected to be completed in late 2010. There can be no assurance that we will be successful in qualifying the new facility under FDA regulations.

Cash used in financing activities was \$973,600 for the first nine months ended September 30, 2010. For 2010, cash used in financing activities was primarily related to our principal payments on the long-term debt in the amount of \$1,200,000. This was partially offset by \$197,243 in proceeds from employee stock option exercises. Cash used in financing activities was \$1,169,501 for the first nine months ended September 30, 2009, primarily as a result of our principal payments on our long-term debt.

#### Critical Accounting Estimates

There have been no significant changes in our critical accounting estimates during the nine months ended September 30, 2010, as compared to the critical accounting estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

#### Recent Accounting Pronouncements

Information with respect to Recent Accounting Pronouncements may be found in Note 3 of Notes to Condensed Consolidated Financial Statements (unaudited) in this Form 10-Q, which information is incorporated herein by reference.

#### Contractual Obligations and Other Commercial Commitments

We have made significant capital investments related to the build-out and validation of our facility in Bedford, Massachusetts. This capital project has been financed with cash on hand and the proceeds of a \$16,000,000 unsecured Credit Agreement with Bank of America entered into on January 31, 2008. This term loan has quarterly principal payments of \$400,000 and a final installment of \$5,200,000 due on the maturity date of December 31, 2015. We commenced making quarterly principal payments on March 31, 2009.

In connection with the acquisition of FAB, the Company entered into a Consent and First Amendment to the Credit Agreement. As part of this amendment, the interest rate for Eurodollar based loans was increased and is payable at a rate based upon (at the Company's election) either Bank of America's prime rate or LIBOR plus 125 basis points. This increased from the original loan amount of prime rate or LIBOR plus 75 basis points. In addition, the Company has pledged to the lender sixty-five percent (65%) of the stock of FAB. Total debt outstanding was \$13,200,000 as of September 30, 2010. Construction of our Bedford, MA facility commenced in May 2007 and validation is expected to be completed in late 2010.

To the extent that funds generated from our operations, together with our existing capital resources, are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.



## ITEM QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

3.

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, 2009.

As of September 30, 2010, 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 ASC 825, Financial Instruments, (formerly SFAS No. 107, Disclosures about Fair Value of Financial Instruments) and Accounting Standards Codification 815, Derivatives and Hedging, (formerly SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities). Our investments consist of money market funds primarily invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, and municipal bonds that are carried on our books at amortized cost, which approximates fair market value.

### Primary Market Risk Exposures

Our primary market risk exposures are in the areas of interest rate risk and currency rate risk. We have three supplier contracts denominated in foreign currencies. Unfavorable fluctuations in exchange rates would have a negative impact on our financial statements. The impact of changes in currency exchange rates for these supplier contracts on our financial statements was immaterial for the nine months ended September 30, 2010. The impact of exchange rates related to the consolidation of the balance sheet amounts related to our FAB subsidiary resulted in an unfavorable currency translation adjustment of (\$1,796,614) during the first nine months of 2010. Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations. As of September 30, 2010, we were subject to interest rate risk on \$13.2 million of variable rate debt. The interest payable on our debt is determined, at the Company's option, based on LIBOR plus 1.25% or the lender's prime rate and, therefore, is affected by changes in market interest rates. Based on the outstanding debt amount as of September 30, 2010, we would have a decrease in future annual cash flows of approximately \$124,000 for every 1% increase in the interest rate over the next twelve month period.

## ITEM CONTROLS AND PROCEDURES

4.

### (a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended, ("Exchange Act"), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and

may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the first nine months of fiscal year 2010 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

## PART II: OTHER INFORMATION

### ITEM LEGAL PROCEEDINGS

1.

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The Complaint alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents.

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

### ITEM RISK FACTORS

1A.

To our knowledge, there have been no material changes in the risk factors described in “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2009, except to the extent additional factual information disclosed elsewhere in this Quarterly Report on Form 10-Q relates to such risk factors. In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2009, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

ITEM 6. EXHIBITS

Exhibit No.	Description
(11)	Statement Regarding Computation of Per Share Earnings
*11.1	See Note 6 to the Financial Statements included herewith.
(31)	Rule 13a-14(a)/15d-14(a) Certifications
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Kevin W. Quinlan pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32)	Section 1350 Certifications
**32.1	Certification of Charles H. Sherwood, Ph.D. and Kevin W. Quinlan, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith.

\*\* Furnished herewith.

SIGNATURES

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

ANIKA THERAPEUTICS, INC.

November 9, 2010

By:

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

25

---