



Anika Therapeutics Reports Second-Quarter 2009 Results

BEDFORD, Mass. --(BUSINESS WIRE)--Jul. 22, 2009-- [Anika Therapeutics, Inc.](#) (Nasdaq: ANIK), a leader in products for tissue protection, healing and repair based on [hyaluronic acid](#) ("HA") technology, today reported financial results for the quarter ended June 30, 2009 .

Key Second-Quarter Highlights

During the second quarter, Anika:

- Completed the evaluation period of its pivotal clinical trial for [MONOVISC™](#) in the United States; On track to complete PMA filing with FDA in 2009
- Signed distribution partner for aesthetic dermatology product in the United States
- Delivered strong year-over-year and sequential sales growth in its joint health care franchise

Revenue

Anika's product revenue increased by 5% to \$8,771,000 for the second quarter of 2009, compared with \$8,379,000 in the same period last year. Product revenue for the first six months of 2009 grew 6% to \$17,290,000 from \$16,246,000 in the first six months of 2008. The increase in product revenue for the quarter and year to date periods was primarily attributable to strong domestic sales of the Company's [ORTHOVISC](#) product line, as well as increases in [MONOVISC](#) sales.

Total revenue for the second quarter of 2009 increased 5% to \$9,524,000 from \$9,060,000 in the second quarter of 2008. Total revenue for the first six months of 2009 increased 6% to \$18,724,000 compared with \$17,609,000 for the same period in 2008.

Product Gross Margin

Product gross margin for the second quarter of 2009 increased to 62% from 57% in last year's second quarter. For the first six months of 2009, product gross margin was 62% compared with 58% for the same period in 2008. The improvement in product gross margin was due to a combination of strong sales in the Company's joint health franchise as well as a favorable product mix.

Other Operating Expenses

Research and development expense increased to \$2,286,000 compared with \$1,645,000 in the same period last year, and \$4,481,000 for this year's six month period versus \$3,153,000 for the same period last year. The increases for both periods were primarily due to the higher expenses for the ongoing U.S. clinical trials for [MONOVISC](#), the commencement of a post-marketing aesthetics dermatology study in people of color, manufacturing validation activities for our Bedford facility, as well as other continuing new product development projects.

Selling, general and administrative expense for the second quarter of 2009 decreased to \$2,736,000 from \$2,880,000 for the same period last year, and \$5,771,000 for this year's six month period versus \$5,949,000 for the same period last year. The decreases for both periods were primarily due to lower personnel costs and marketing expenses, which more than offset the increase in operating expenses related to the new manufacturing facility in Bedford.

Net Income

Net income for the second quarter of 2009 grew 18% to \$956,000, or \$0.08 per diluted share, from \$813,000,

or \$0.07 per diluted share, for the same period last year. Net income for the first six months of 2009 increased 3% to \$1,478,000, or \$0.13 per diluted share, from \$1,430,000, or \$0.12 per diluted share, for the first six months of 2008.

Other

Anika's cash and cash equivalents at June 30, 2009 were \$39,550,000 compared with \$43,194,000 at December 31, 2008. The decrease in cash was due primarily to capital expenditures on its Bedford facility, principal and interest payments on the Company's debt, and inventory build needed in preparation for relocating some of the equipment to the Bedford facility.

Management Commentary

"We generated steady sequential and year-over-year top-line growth in the second quarter of the year, driven by strong domestic sales of our flagship joint health product, ORTHOVISC," said Charles H. Sherwood, Ph.D., Anika's president and chief executive officer. "In fact, our commercialization partner, DePuy Mitek, delivered a 34% year-over-year increase in unit growth to a record quarterly level."

"During the quarter we completed the clinical segment of the U.S. pivotal trial for MONOVISC, our single-injection osteoarthritis product," Sherwood said. "We are now focused on completing the retreatment study for MONOVISC, which is designed to evaluate the benefit of repeat treatments. All of our target patient population have been retreated, and we expect to complete this follow-on study around the end of the third quarter. We have already filed two of four modules for the PMA for MONOVISC and are on schedule to file the remaining two with the FDA by the end of the year. We are very enthusiastic about the prospects for this innovative product."

"Another key operational highlight of the second quarter was the signing of an exclusive U.S. distribution agreement with Coapt Systems for our aesthetic dermatology franchise," said Sherwood. "Coapt has a complementary product line and a sales force that is highly experienced in the technical sales of facial aesthetic products, particularly to plastic surgeons. They have completed sales training with more than 50 sales professionals, and we expect Coapt Systems to relaunch our product in the current third quarter."

"Based on our first-half financial performance and our outlook for the second half of the year, we continue to expect to generate good revenue growth and improved profitability in 2009," said Sherwood. "Looking further ahead, we are confident that the investments we are making in Anika will result in accelerated growth in 2010 and beyond."

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights and outlook on Thursday, July 23, 2009 at 9:00 a.m. ET. In addition, the Company will answer questions concerning business and financial developments and trends, and other business and financial matters affecting the Company, some of the responses to which may contain information that has not been previously disclosed.

To listen to the conference call, dial 866-356-3377 (International callers dial 617-597-5392) and use the passcode 85495129. Please call approximately 10 minutes before the starting time and reference Anika Therapeutics. In addition, the conference call will be available to interested parties through a live audio Internet broadcast at www.anikatherapeutics.com. The call will be archived and accessible on the same website shortly after the conclusion of the call.

About Anika Therapeutics, Inc.

Headquartered in Bedford, Mass., [Anika Therapeutics, Inc.](http://www.anikatherapeutics.com) 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. Anika's products include [ORTHOVISC®](#), a treatment for osteoarthritis of the knee available internationally and marketed in the U.S. by DePuy Mitek; [HYVISC®](#), a treatment for equine osteoarthritis marketed in the U.S. by Boehringer Ingelheim Vetmedica, Inc.; a family of aesthetic dermatology products for facial wrinkles and scar remediation marketed in the U.S. by Coapt Systems, Inc.; [AMVISC®](#), [AMVISC® Plus](#), [STAARVISC™-II](#) and [Shellgel™](#) injectable viscoelastic HA products for ophthalmic surgery; [INCERT®](#), an HA-based anti-adhesive for surgical applications; [ORTHOVISC®mini](#) a treatment for osteoarthritis targeting small joints and available in Europe; [MONOVISC™](#) a single-injection osteoarthritis product based on Anika's proprietary cross-linking technology and also available in Europe and Turkey; and next generation

products for joint health and aesthetic dermatology based on the Company's proprietary, chemically modified HA.

The statements made in this press release which are not statements of historical fact are 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, without limitation, statements that may be identified by words such as "expectations," "remains," "focus," "expected," "prospective," "expanding," "building," "continue," "progress," "plan," "efforts," "hope," "believe," "objectives," "opportunities," "will," "seek," "expect" and other expressions which are predictions of or indicate future events and trends and which do not constitute historical matters identify forward-looking statements. These statements also include: (i) the company's expectations concerning its MONOVISC product, including the U.S. clinical trials and the filing of a PMA, and its expectations to reap significant financial rewards for moving the product through the pipeline, (ii) expectations regarding Coapt Systems including timing to begin selling Hydrelle, (iii) statements concerning revenue and income performance in 2009, and (iv) expectations that Anika's investments will result in accelerated growth in 2010 and beyond. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks, uncertainties and other factors. The company's actual results could differ materially from any anticipated future results, performance or achievements described in the forward-looking statements as a result of a number of factors including: (i) Coapt Systems ability to effectively sell Hydrelle; (ii) the company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all, obtain clinical data to support a pre-market approval application or timely file and receive FDA or other regulatory approvals of its products, or that such approvals will not be obtained in a timely manner or without the need for additional clinical trials; (iii) the company's research and product development efforts and their relative success, including whether the company has any meaningful sales of any new products resulting from such efforts; (iv) the cost effectiveness and efficiency of our manufacturing operations and production planning; (v) the strength of the economies in which the company operates or will be operating, as well as the political stability of any of those geographic areas (vi) future determinations by the company to allocate resources to products and in directions not presently contemplated or (vii) the company's ability to launch MONOVISC in the U.S., if at all. Any delay in receiving any regulatory approvals may adversely affect the company's competitive position. Even if regulatory approvals are obtained, there is a risk that meaningful sales of the products may not be achieved. There is also a risk that (i) the company's existing distributors or customers will not continue to place orders at historical levels or that any of them will seek to modify or terminate existing arrangements, (ii) the company's efforts to enter into long-term marketing and distribution arrangements, including with new international distributors for ORTHOVISC and MONOVISC, will not be successful, (iii) new distribution arrangements will not result in meaningful sales of the company's products, (iv) the company's distributors will be unable to achieve performance and sales threshold milestones in its distribution agreements, (v) competitive products will adversely impact the company's product sales, (vi) the estimated size(s) of the markets which the company has targeted its products will fail to be achieved, (vii) 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 results of operations, or (viii) increased sales of the company's products, including HYVISC, ORTHOVISC, or its ophthalmic products, will not continue or sales will decrease or not reach historical sales levels, or even if such increases occur that such increases will improve gross margins, any of which may have a material adverse effect on the company's business and operations. Certain other factors that might cause the company's actual results to differ materially from those in the forward-looking statements include those set forth under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the company's Annual Report on Form 10-K for the year ended December 31, 2008 and on Form 10-Q for the period ended March 31, 2009, as well as those described in the company's other press releases and SEC filings.

Anika Therapeutics, Inc. and Subsidiary
 Consolidated Statements of Operations
 (unaudited)

	Quarter Ended		Six Months Ended	
	June 30,		June 30,	
	2009	2008	2009	2008
Product revenue	\$8,770,763	\$8,378,936	\$17,289,836	\$16,246,465

Licensing, milestone and contract revenue	752,913	681,253	1,434,164	1,362,503
Total revenue	9,523,676	9,060,189	18,724,000	17,608,968
Operating expenses:				
Cost of product revenue	3,294,160	3,644,530	6,505,826	6,860,600
Research & development	2,286,229	1,644,619	4,480,537	3,152,959
Selling, general & administrative	2,735,552	2,880,156	5,770,534	5,948,772
Total operating expenses	8,315,941	8,169,305	16,756,897	15,962,331
Income from operations	1,207,735	890,884	1,967,103	1,646,637
Interest income (expense), net	(1,382)	157,875	58	347,281
Income before income taxes	1,206,353	1,048,759	1,967,161	1,993,918
Provision for income taxes	250,579	235,830	488,667	563,431
Net income	\$955,774	\$812,929	\$1,478,494	\$1,430,487
Basic net income per share:				
Net income	\$0.08	\$0.07	\$0.13	\$0.13
Basic weighted average common shares outstanding	11,384,949	11,327,457	11,375,798	11,276,871
Diluted net income per share:				
Net income	\$0.08	\$0.07	\$0.13	\$0.12
Diluted weighted average common shares outstanding	11,548,079	11,516,177	11,517,949	11,502,720

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

	June 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$39,549,558	\$43,193,655
Accounts receivable, net	6,456,273	5,418,421
Inventories	7,304,711	5,519,754
Current portion deferred income taxes	1,235,364	1,235,364
Prepaid expenses and other	505,054	463,284
Total current assets	55,050,960	55,830,478
Property and equipment, at cost	44,175,496	42,436,827
Less: accumulated depreciation	(10,829,226)	(10,190,144)
	33,346,270	32,246,683
Long-term deposits and other	351,477	506,787
Intangible asset, net	906,863	936,275

Deferred income taxes	6,302,507	6,300,665
Total Assets	\$95,958,077	\$95,820,888

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable	\$1,769,194	\$2,375,340
Accrued expenses	3,151,745	2,325,219
Deferred revenue, current	2,756,330	2,732,293
Long-term debt, current	1,600,000	1,600,000
Income taxes payable	208,811	—
Other long-term liabilities	879,669	831,051
Long-term deferred revenue	9,449,996	10,800,001
Long-term debt	13,600,000	14,400,000
Total liabilities	33,415,745	35,063,904
Stockholders' equity		
Preferred stock	—	—
Common stock	114,380	113,776
Additional paid-in-capital	43,167,479	42,861,229
Retained earnings	19,260,473	17,781,979
Total stockholders' equity	62,542,332	60,756,984
Total Liabilities and Stockholders' Equity	\$95,958,077	\$95,820,888

Anika Therapeutics, Inc. and Subsidiary
Supplemental Financial Data -
(unaudited)

Revenue by Product Line and Product Gross Margin

	Quarter Ended June 30,				Six Months Ended June 30,			
	2009	% Ttl	2008	% Ttl	2009	% Ttl	2008	% Ttl
Joint Health	\$5,568,685	64 %	\$4,765,474	57 %	\$10,718,327	62 %	\$8,887,654	55 %
Ophthalmic	2,480,923	28 %	2,562,218	31 %	5,126,175	30 %	5,580,889	34 %
Veterinary	611,600	7 %	1,020,394	12 %	1,248,935	7 %	1,721,017	11 %
Other	109,555	1 %	30,850	0 %	196,399	1 %	56,905	0 %
	\$8,770,763	100 %	\$8,378,936	100 %	\$17,289,836	100 %	\$16,246,465	100 %

Product gross profit	\$5,476,603		\$4,734,406		\$10,784,010		\$9,385,865	
Product gross margin	62.4 %		56.5 %		62.4 %		57.8 %	

Product Revenue by Geography

	Quarter Ended June 30,				Six Months Ended June 30,			
	2009	% Ttl	2008	% Ttl	2009	% Ttl	2008	% Ttl
Domestic	\$6,461,662	74 %	\$5,963,233	71 %	\$12,597,226	73 %	\$12,117,344	75 %

International	2,309,101	26 %	2,415,703	29 %	4,692,610	27 %	4,129,121	25 %
	\$8,770,763	100%	\$8,378,936	100%	\$17,289,836	100%	\$16,246,465	100%

Source: Anika Therapeutics, Inc.

Anika Therapeutics, Inc.

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CEO

or

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CFO

<https://ir.anika.com/Anika-Therapeutics-Reports-Second-Quarter-2009-Results>