Anika Therapeutics Reports 17% Revenue Growth in Third-Quarter 2009

BEDFORD, Mass. --(BUSINESS WIRE)--Oct. 27, 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 September 30, 2009 .

Key Third-Quarter Highlights

During the third quarter, Anika:

- Grew net income by 37% year over year
- Increased total revenue and product revenue by 17% and 18%, respectively
- Grew joint health revenue by 31%
- Launched MONOVISC™ in Canada
- Made progress toward filing MONOVISC PMA by end of 2009
- Launched Hydrelle™ in United States through Coapt Systems

Revenue

Anika's product revenue increased by 18% to $10,087,000 for the third quarter of 2009, compared with $8,524,000 in the same period last year. Product revenue for the first nine months of 2009 grew 11% to $27,377,000 from $24,770,000 in the first nine months of 2008. The increase in product revenue for the quarter and year-to-date periods was attributable to strong sales of the Company's ORTHOVISC® product line.

Total revenue for the third quarter of 2009 increased 17% to $10,793,000 from $9,205,000 in the third quarter of 2008. Total revenue for the first nine months of 2009 increased 10% to $29,517,000 compared with $26,814,000 for the same period in 2008.

Product Gross Margin

Product gross margin for the third quarter of 2009 increased to 65% from 59% in last year's third quarter. For the first nine months of 2009, product gross margin was 63% compared with 58% for the same period in 2008. The improvement in product gross margin was due to product mix as well as increased manufacturing activity in preparation for moving operations to the Bedford facility.

Other Operating Expenses

Research and development expenses increased to $2,382,000 compared with $1,802,000 in the same period last year, and $6,863,000 for this year's nine-month period compared to $4,955,000 for the same period last year. The increases for both periods were due to higher regulatory and clinical development expenses as a result of the ongoing U.S. clinical trials for MONOVISC, the post-marketing aesthetics dermatology study in people of color, manufacturing validation activities for the new manufacturing facility in Bedford, as well as other continuing new product development projects.

Selling, general and administrative expenses for the third quarter of 2009 increased to $2,843,000 from $2,567,000 for the same period last year, and $8,614,000 for this year's nine-month period compared to $8,516,000 for the same period last year. The quarter's increase was due to higher professional costs. Operating expenses related to the Bedford facility were flat year-over-year.

Net Income

Net income for the third quarter of 2009 grew 37% to $1,512,000, or $0.13 per diluted share, from $1,104,000, or $0.10 per diluted share, for the same period last year. Net income for the first nine months of 2009 increased 18% to $2,990,000, or $0.26 per diluted share, from $2,535,000, or $0.22 per diluted share, for the first nine months of 2008.

Other

Anika's cash and cash equivalents at September 30, 2009 were $38,540,000 compared with $43,194,000 at December 31, 2008. The decrease in cash was due primarily to capital expenditures at Anika's Bedford facility, principal and interest payments on the Company's debt, increase in accounts receivable, and inventory build needed in preparation for relocating the existing manufacturing equipment to the Bedford facility.

Management Commentary

"Anika reported excellent results in the third quarter with a 37% increase in net income on 17% revenue growth," said Charles Sherwood, Ph.D., Anika's president and chief executive officer. "Our joint health franchise continues to be the key driver of Anika's growth, with revenue from that franchise up 31% year over year. Domestically, we recorded very strong ORTHOVISC sales, continuing to grow our share of that market. We expect to increase our U.S. market share to about 12% by the end of 2009."

"We continue to be excited about the prospects for our single-injection osteoarthritis product, MONOVISC," said Sherwood. "We introduced MONOVISC in the third quarter to the Canadian market through Anika's long-term ORTHOVISC distribution partner and we continue to receive product inquiries in new markets, such as Eastern Europe and Asia. We recently completed the MONOVISC re-treatment study and are on-track to complete our PMA filing by the end of the year."

"During the third quarter, we also launched our aesthetics dermatology product, Hydrelle, in the United States through our exclusive distribution partner, Coapt Systems," Sherwood said. "In addition to the Hydrelle launch, we are working on expanding our aesthetic franchise with the development of a lighter version of our product to be used for the treatment of fine lines. We have filed for CE Mark approval and plan to launch the new product at the beginning of 2010 in Europe. Additionally, we are in discussions with the FDA about the pathway for approval for the fine-line product domestically."

"As we head into the fourth quarter, we are confident that we will deliver good revenue growth and improved profitability for full year 2009," said Sherwood. "Looking ahead, we believe that we are well positioned to benefit from the investments we have made during the past year. We also have a strong balance sheet and cash generating ability that enables us to capitalize on exciting growth opportunities and fulfill our joint health vision to alleviate pain, repair and restore damaged tissue for long-term patient benefit."

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights and outlook on Wednesday, October 28, 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 800-798-2801 (International callers dial 617-614-6205) and use the passcode 12413497. 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. 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 available in Europe, Turkey, and Canada; 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) expectations for increased market share to 12% at the end of 2009; (ii) the Company's expectations concerning its MONOVISC product, including the U.S. clinical trials and the filing of a PMA, (iii) the development of a lighter version of our aesthetic product to be used for the treatment of fine lines, and expectations regarding the filing for a CE Mark approval, receiving approval, and planning to launch the new product at the beginning of 2010 in Europe; (iv) discussions with the FDA about the pathway for approval for the fine-line product domestically;(v) expectations regarding achieving good revenue growth and improved profitability for full year 2009; (vi) expectations that the Company is well positioned to benefit from investments; and (vii) the Company's ability to capitalize on exciting growth opportunities and fulfill its joint health vision to alleviate pain, repair and restore damaged tissue. 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 endedJune 30, 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		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Product revenue	$10,087,130	$8,523,765	$27,376,966	$24,770,230
Licensing, milestone and contract revenue	705,634	681,250	2,139,798	2,043,753
Total revenue	10,792,764	9,205,015	29,516,764	26,813,983
Operating expenses:				
Cost of product revenue	3,551,374	3,504,986	10,057,200	10,365,586
Research & development	2,382,146	1,801,561	6,862,683	4,954,520
Selling, general & administrative	2,842,991	2,567,000	8,613,525	8,515,772
Total operating expenses	8,776,511	7,873,547	25,533,408	23,835,878
Income from operations	2,016,253	1,331,468	3,983,356	2,978,105
Interest income (expense), net	(44,096)	130,486	(44,038)	477,767
Income before income taxes	1,972,157	1,461,954	3,939,318	3,455,872
Provision for income taxes	460,232	357,751	948,899	921,182
Net income	$1,511,925	$1,104,203	$2,990,419	$2,534,690
Basic net income per share:				
Net income	$0.13	$0.10	$0.26	$0.22
Basic weighted average common shares outstanding	11,385,679	11,329,422	11,379,128	11,294,928
Diluted net income per share:				
Net income	$0.13	$0.10	$0.26	$0.22
Diluted weighted average common shares outstanding	11,575,907	11,485,989	11,535,721	11,479,797

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

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$38,540,295	$43,193,655
Accounts receivable, net	7,982,193	5,418,421
Inventories	6,951,192	5,519,754
Current portion deferred income taxes	1,235,364	1,235,364
Prepaid expenses and other	403,214	463,284

Total current assets	55,112,258	55,830,478
Property and equipment, at cost	44,875,631	42,436,827
Less: accumulated depreciation	(11,143,723)	(10,190,144)
	33,731,908	32,246,683
Long-term deposits and other	345,353	506,787
Intangible asset, net	892,157	936,275
Deferred income taxes	6,392,976	6,300,665
Total Assets	$96,474,652	$95,820,888
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$1,220,652	$2,375,340
Accrued expenses	3,285,842	2,325,219
Deferred revenue, current	2,747,115	2,732,293
Long-term debt, current	1,600,000	1,600,000
Income taxes payable	376,547	—
Other long-term liabilities	939,699	831,051
Long-term deferred revenue	8,774,996	10,800,001
Long-term debt	13,200,000	14,400,000
Total liabilities	32,144,851	35,063,904
Stockholders' equity:		
Preferred stock	—	—
Common stock	114,378	113,776
Additional paid-in-capital	43,443,025	42,861,229
Retained earnings	20,772,398	17,781,979
Total stockholders' equity	64,329,801	60,756,984
Total Liabilities and Stockholders' Equity	$96,474,652	$95,820,888

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

Revenue by Product Line and Product Gross Margin

	Quarter Ended September 30,				Nine Months Ended September 30,			
	2009	% Ttl	2008	% Ttl	2009	% Ttl	2008	% Ttl
Joint Health	$6,136,101	61 %	$4,676,247	55 %	$16,854,428	61 %	$13,563,901	55 %
Ophthalmic	2,705,897	27 %	2,703,095	32 %	7,832,072	29 %	8,283,984	33 %
Veterinary	584,709	6 %	706,553	8 %	1,833,644	7 %	2,427,570	10 %
Aesthetics	623,358	6 %	383,320	4 %	761,532	3 %	399,370	2 %
Other	37,065	0 %	54,550	1 %	95,290	0 %	95,405	0 %
	$10,087,130	100%	$8,523,765	100%	$27,376,966	100%	$24,770,230	100%
Product gross profit	$6,535,756		$5,018,779		$17,319,766		$14,404,644	

Product gross margin	64.8	%	58.9	%	63.3	%	58.2	%

Product Revenue by Geography

	Quarter Ended September 30,				Nine Months Ended September 30,			
	2009	% Ttl	2008	% Ttl	2009	% Ttl	2008	% Ttl
Domestic	$7,317,404	73 %	$6,062,837	71 %	$19,914,630	73 %	$18,180,180	73 %
International	2,769,726	27 %	2,460,928	29 %	7,462,336	27 %	6,590,050	27 %
	$10,087,130	100%	$8,523,765	100%	$27,376,966	100%	$24,770,230	100%

Source: Anika Therapeutics, Inc.

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