Anika Investor Relations

Anika Therapeutics Reports 18% Revenue Growth in Fourth-Quarter 2009

BEDFORD, Mass., Mar 16, 2010 (BUSINESS WIRE) -- 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 and year ended December 31, 2009.

Key Highlights

- Obtained robust growth platform with acquisition of Fidia Advanced Biopolymers
- Increased total revenue and product revenue by 18% and 20% in fourth quarter, respectively
- Joint health revenue grew by 17% in fourth quarter and 22% for the full year, driven by strong domestic sales of ORTHOVISC
- Submitted final module for MONOVISC PMA filing with FDA

Revenue

Anika's product revenue increased by 20% to $9,944,000 for the fourth quarter of 2009, compared with $8,285,000 in the same period last year. Product revenue for the full year of 2009 grew 13% to $37,321,000 from $33,055,000 in 2008. The increase in product revenue for the quarter and year-end periods was attributable to strong sales of the Company's ORTHOVISC® product line, as well as increased aesthetic dermatology product sales.

Total revenue for the fourth quarter of 2009 increased 18% to $10,619,000 from $8,966,000 in the fourth quarter of 2008. Total revenue for the full year of 2009 increased 12% to $40,136,000 compared with $35,780,000 in 2008.

Product Gross Margin

Product gross margin for the fourth quarter of 2009 was 64% compared with 66% in last year's fourth quarter. For full year 2009, product gross margin was 63% compared with 60% in 2008. The full year 2009 increase in product gross margin was due to favorable product mix as well as increased manufacturing activity in preparation for moving operations to the Bedford facility.

Operating Expenses

Research and development expenses decreased to $1,319,000 in the fourth quarter compared with $2,445,000 in the same period last year, and increased to $8,182,000 for full year 2009 from $7,399,000 for 2008. The year-over-year decrease in the fourth quarter was due to the completion of the U.S. MONOVISC clinical trial in the third quarter. The full-year 2009 increase was due to higher regulatory and clinical development expenses as a result of the MONOVISC clinical trial, the post-marketing aesthetics dermatology study in people of color, as well as other continuing new product development projects.

Selling, general and administrative expenses for the fourth quarter of 2009 increased to $2,843,000 from $2,450,000 for the same period last year, and decreased to $10,545,000 for the full year 2009 from $10,965,000 in 2008. The increase for the fourth quarter was due to higher personnel, legal and new facility costs, while the decrease for the full year 2009 was due to lower marketing costs as the Company had incurred significant costs in 2008 related to the European launch of MONOVISC and ORTHOVISC mini.

In the fourth quarter of 2009, Anika recorded $1,241,000 in expenses related to its recent acquisition of Fidia Advanced Biopolymers, s.r.l. ("FAB"), formerly a wholly-owned subsidiary of privately held Italian pharmaceutical company, Fidia Farmaceutici S.p.A. For full year 2009, Anika recorded $2,152,000 in acquisition-related expenses.

Net Income

Net income for the fourth quarter of 2009 was $697,000, or $0.06 per diluted share. Net income for full year 2009 was $3,688,000, or $0.32 per diluted share,

Excluding acquisition-related expenses, non-GAAP net income for the fourth quarter of 2009 would have been $2,026,000, or $0.17 per diluted share. This is an 85% increase from $1,095,000, or $0.10 per diluted share, for the fourth quarter of 2008. Non-GAAP net income for full year 2009 would have been or $5,527,000, or $0.48 per share. This represents a 52% increase from $3,629,000, or $0.32 per diluted share, for full year 2008.

Other

Anika's cash and cash equivalents at December 31, 2009 were $24,427,000 compared with $43,194,000 at December 31, 2008. The decrease in cash was due primarily to the acquisition of FAB as well as 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

"In a year that culminated with the transformative acquisition of Fidia Advanced Biopolymers (FAB), Anika performed well financially and achieved many important strategic milestones," said Charles Sherwood, Ph.D., Anika's president and chief executive officer. "In 2009, we grew overall revenue 12% to $40.1 million. We also completed our seventh-consecutive profitable year, while making significant investments in infrastructure and product development."

"Anika concluded this year of achievement with another quarter of year-over-year top-line growth," Sherwood said. "Our joint health franchise continued to perform in-line with our high expectations with excellent domestic sales of ORTHOVISC. During the quarter, we completed our PMA filing for MONOVISC, our single-injection joint health product, with the FDA. We continue to be enthusiastic about the prospects for this innovative product."

"Clearly, the landmark event of the quarter was our acquisition of FAB," Sherwood continued. "FAB provides Anika with an exciting new growth platform and advances our vision to offer therapeutic products that go beyond pain relief to protect and restore damaged tissue. Once approved, we expect that FAB's joint health product portfolio along with MONOVISC will provide our direct commercialization team with a critical mass of products to sell into the U.S. market."

"As we look to 2010 and beyond, we are well positioned to benefit from the significant investments we have made in our future and the milestones we achieved during the past year," said Sherwood. "We have six key goals for 2010: develop our direct sales model and launch MONOVISC domestically upon its approval by the FDA; obtain approval and launch key FAB orthopedic products in the United States; complete the total transfer of our manufacturing operations to Bedford; expand FAB's innovative tissue technology product beyond Italy into other areas of Europe; continue to grow sales of ORTHOVISC and MONOVISC worldwide; and reduce FAB's operating loss through cost synergies and product rationalization, positioning us to generate profits from FAB in 2011."

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights and outlook on Wednesday, March 17, 2010 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 866-383-8119 (International callers dial 617-597-5344) and use the passcode 83084058. 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 range from orthopedic/joint health solutions led by ORTHOVISC®, a treatment for osteoarthritis of the knee; to surgical aids in the ophthalmic and anti-adhesion fields. The company also offers aesthetic dermal fillers for the correction of

facial wrinkles. Anika's Italian subsidiary, Fidia Advanced Biopolymers, S.r.l (FAB), provides complementary HA products in orthopedic/joint health and anti-adhesion, as well as therapeutics in new areas such as advanced wound treatment and ear, nose and throat care. FAB's regenerative tissue technology advances Anika's vision to offer therapeutic products that go beyond pain relief to protect and restore damaged tissue.

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 trendsdo not constitute historical matters and identify forward-looking statements.These statements also include those relating to: (i) the expectation that FAB's joint health product portfolio will provide the hybrid sales force Anika is building with a critical mass of products to sell into the U.S. market, (ii) the achievement of final regulatory approvals for full manufacturing in Anika's Bedford facility, (iii) increasing revenue growth and maintaining profitability, (iv) obtaining PMA approval for MONOVISC in the United States, (v) building Anika's hybrid commercialization capability and launching MONOVISC domestically, (vi) continuing the worldwide expansion of ORTHOVISC and MONOVISC through new partnerships and regulatory approvals, and (vii) completing the FAB integration and gaining approval of three of FAB's joint health products in the United States.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, 2009, as well as those described in the Company's other press releases and SEC filings.

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

	Quarter Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
Product revenue	$9,943,940	$8,284,557	$37,320,906	$33,054,787
Licensing, milestone and contract revenue	675,000	681,247	2,814,798	2,725,000

Total revenue	10,618,940	8,965,804	40,135,704	35,779,787
Operating expenses:				
Cost of product revenue	3,613,028	2,822,930	13,670,228	13,188,516
Research & development	1,318,849	2,444,529	8,181,532	7,399,049
Selling, general & administrative	2,842,979	2,449,721	10,545,351	10,965,493
Acquisition-related expenses	1,240,701	--	2,151,854	--
Total operating expenses	9,015,557	7,717,180	34,548,965	31,553,058
Income from operations	1,603,383	1,248,624	5,586,739	4,226,729
Interest income (expense), net	(30,442)	20,745	(74,480)	498,512
Income before income taxes	1,572,941	1,269,369	5,512,259	4,725,241
Provision for income taxes	875,793	174,864	1,824,692	1,096,046
Net income	$697,148	$1,094,505	$3,687,567	$3,629,195
Basic net income per share:				
Net income	$0.06	$0.10	$0.32	$0.32
Basic weighted average common shares outstanding	11,408,790	11,352,383	11,386,989	11,308,124
Diluted net income per share:				
Net income	$0.06	$0.10	$0.32	$0.32
Diluted weighted average common shares outstanding	11,653,048	11,456,691	11,562,304	11,460,801

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

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$24,426,990	$43,193,655
Accounts receivable, net	11,831,438	5,418,421
Inventories	8,441,079	5,519,754
Current portion of deferred income taxes	2,183,827	1,235,364
Prepaid expenses and other	2,921,283	463,284
Total current assets	49,804,617	55,830,478
Property and equipment, at cost	47,172,403	42,436,827
Less: accumulated depreciation	(11,424,788)	(10,190,144)
	35,747,615	32,246,683
Long-term deposits and other	413,228	506,787
Intangible assets, net	33,577,451	936,275
Deferred income taxes	3,506,362	6,300,665
Goodwill	7,652,253	--
Total Assets	$130,701,526	$95,820,888

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable	$6,366,944	$2,375,340
Accrued expenses	5,816,170	2,325,219
Deferred revenue, current	2,751,467	2,732,293
Long-term debt, current	1,600,000	1,600,000
Total current liabilities	16,534,581	9,032,852
Other long-term liabilities	1,818,383	831,051
Long-term deferred revenue	8,099,996	10,800,001
Deferred tax liability	9,305,064	--
Long-term debt	12,800,000	14,400,000
Stockholders' equity		
Preferred stock	--	--
Common stock	134,188	113,776
Additional paid-in-capital	60,539,768	42,861,229
Retained earnings	21,469,546	17,781,979
Total stockholders' equity	82,143,502	60,756,984
Total Liabilities and Stockholders' Equity	$130,701,526	$95,820,888

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

Revenue by Product Line and Product Gross Margin

	Quarter Ended December 31,				Twelve Months Ended December 31,			
	2009	% Ttl	2008	% Ttl	2009	% Ttl	2008	% Ttl
Joint Health	$6,025,471	61%	$5,143,768	62%	$22,879,899	61%	$18,707,669	57%
Ophthalmic	2,741,843	28%	2,394,631	29%	10,573,915	29%	10,678,615	32%
Veterinary	440,838	4%	600,880	7%	2,274,482	6%	3,028,450	9%
Aesthetics	709,633	7%	105,903	2%	1,471,165	4%	505,273	2%
Other	26,155	0%	39,375	0%	121,445	0%	134,780	0%
	$9,943,940	100%	$8,284,557	100%	$37,320,906	100%	$33,054,787	100%
Product gross profit	$6,330,912		$5,461,627		$23,650,678		$19,866,271	
Product gross margin	64%		66%		63%		60%	

Product Revenue by Geography

	Quarter Ended December 31,				Twelve Months Ended December 31,			
	2009	% Ttl	2008	% Ttl	2009	% Ttl	2008	% Ttl
Domestic	$7,549,285	76%	$5,884,332	71%	$27,463,915	74%	$24,064,512	73%
International	2,394,655	24%	2,400,225	29%	9,856,991	26%	8,990,275	27%
	$9,943,940	100%	$8,284,557	100%	$37,320,906	100%	$33,054,787	100%

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of Reported GAAP Results to Non-GAAP Financial Measures
(unaudited)

	Quarter Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
GAAP net income, as reported	$697,148	$1,094,505	$3,687,567	$3,629,195
Acquisition-				

related expenses	1,240,701	-	2,151,854	-
Tax impact of adjustment	91,208	-	(312,450)	-
Non-GAAP net income	$2,029,057	$1,094,505	$5,526,971	$3,629,195
Diluted net income per share:				
As reported	$0.06	$0.10	$0.32	$0.32
Non GAAP	$0.17	$0.10	$0.48	$0.32
Weighted average number of common shares:				
Diluted	11,653,048	11,456,691	11,562,304	11,460,801

Within this news release the company is using non-GAAP net income.This is a non-GAAP financial measure and is intended to serve as a complement to results provided in accordance with accounting principles generally accepted in the United States.Anika Therapeutics believes that such information provides a consistent historical comparison of the Company's performance.

SOURCE: Anika Therapeutics, Inc.

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