

Anika Therapeutics Reports 39% Total Revenue Growth in Fourth Quarter 2010

BEDFORD, Mass., Mar 09, 2011 (BUSINESS WIRE) --

<u>Anika Therapeutics, Inc.</u> (Nasdaq: ANIK), a leader in products for tissue protection, healing, and repair, based on <u>hyaluronic acid</u> ("HA") technology, today reported financial results for the quarter and full year ended December 31, 2010.

Business Highlights

- Product revenue up 43% for the fourth quarter
- Fourth quarter Orthobiologics revenue rises 40%, driven by strong U.S. sales of ORTHOVISC®
- Company receives FDA approval to launch ophthalmic product, ANIKAVISC®
- MONOVISC TM continues to perform well in Europe

Revenue

Anika's consolidated product revenue increased 43% to \$14.2 million for the fourth quarter of 2010, from \$9.9 million in the fourth quarter of 2009. Consolidated product revenue for the full year 2010 rose 41% to \$52.7 million from \$37.3 million in 2009.

Excluding revenue from Fidia Advanced Biopolymers, s.r.l. ("FAB"), which was acquired by Anika at the end of 2009 and is now renamed as Anika Therapeutics S.r.l., product revenue grew 17% for the fourth quarter of 2010 and 18% for the full year, as compared with the comparable periods in 2009.

In addition to the revenue contributed by FAB products, Anika's consolidated and organic product revenue growth for both periods was primarily driven by continued strong U.S. sales of the Company's ORTHOVISC® product line as well as increased contribution from international sales of MONOVISCTM.

Total revenue for the fourth quarter of 2010 increased 39% to \$14.7 million, from \$10.6 million in the year-earlier quarter. For the full year 2010, total revenue grew 38% to \$55.6 million from \$40.1 million in 2009.

Product Gross Margin

Product gross margin for the fourth quarter of 2010 was 53%, compared with 64% in the fourth quarter of 2009. For full-year 2010, Anika's product gross margin was 55%, compared with 63% last year. The decrease in product gross margin for both periods largely reflected the addition of FAB products, which have lower gross margins, into Anika's overall product mix, and was also negatively affected by inventory reserves and duplicate manufacturing expenditures during the transition from Woburn to the Company's Bedford, Massachusetts, facility.

Operating Expenses

Research and development expenses for the fourth quarter of 2010 were \$1.4 million, compared with \$1.3 million in the fourth quarter of 2009, as the added R&D from FAB was offset by lower clinical trial costs for the quarter. For full-year 2010, research and development expenses decreased 16% to \$6.9 million, from \$8.2 million last year. The decrease primarily resulted from the conclusion of Anika's MONOVISC clinical trials in the third quarter of 2009, partially offset by the added FAB R&D expenses.

Selling, general and administrative expenses for the fourth quarter of 2010 were \$4.2 million, compared with \$4.1 million in the same quarter of 2009, as the added FAB costs were matched by acquisition costs incurred by

Anika in the fourth quarter of 2009. For full-year 2010, selling, general and administrative expenses increased to \$17.3 million from \$12.7 million in 2009, reflecting the inclusion of FAB's operations in 2010. Selling, general and administrative expenses for 2009 included \$2.1 million of acquisition related costs.

Operating and Net Income

Operating income for the fourth quarter of 2010 grew 55% to \$2.5 million, from \$1.6 million in the same period in 2009. For full-year 2010, operating income rose 35% to \$7.5 million, from \$5.6 million last year.

Net income for the fourth quarter of 2010 increased to \$1.4 million, or \$0.10 per diluted share, from \$700,000, or \$0.06 per diluted share, for the same period in 2009. Anika's full-year 2010 net income was \$4.3 million, or \$0.32 per diluted share, compared with \$3.7 million, or \$0.32 per diluted share in 2009. The Company's tax rate for 2010 was 41.2% versus 33.1% for 2009 due to the impact of FAB's losses on our consolidated blended rate, as well as lower investment tax credits and R&D credits in 2010 versus 2009. The comparison with the fourth quarter and full year was also negatively impacted by the dilutive effect of an additional 2 million shares outstanding as a result of the FAB acquisition.

Cash and Cash Equivalents

Anika's cash and cash equivalents at December 31, 2010 were \$28.2 million, compared with \$24.4 million at December 31, 2009. The increase was due primarily to growth in income from operations.

Management Commentary

"Anika concluded 2010 with another strong quarter on the top line and further progress toward accomplishment of our key goals," said Charles H. Sherwood, Ph.D., president and chief executive officer. "Driven by increasing demand for ORTHOVISC, it was our 14th consecutive quarter of year-over-year product revenue growth. MONOVISC continues to sell well in Europe as we continue to work towards U.S. approval. FAB's advanced wound care and orthopedic products are also driving growth, and we are working to expand the distribution of FAB's restorative tissue products internationally and advanced wound care products in the U.S. Our integration of FAB remains on track, and we have targeted their operations to achieve breakeven in 2011. In addition, we recently took the first steps toward positioning Anika to successfully build its ophthalmic product franchise over the long term by launching our own branded product, ANIKAVISC®. We look forward to reporting continued operational progress as well as growth in margins and earnings in 2011."

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights and outlook tomorrow, Thursday, March 10, 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 866-202-4367 (International callers dial 617-213-8845) and use the passcode 69151063. Please call approximately 10 minutes before the starting time and reference Anika Therapeutics. In addition, the conference call will be available through a live audio webcast in the "Investor Relations" section of the Anika Therapeutics website, www.anikatherapeutics.com. An accompanying slide presentation also can be accessed via the Anika Therapeutics website. The conference 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., <u>Anika Therapeutics</u>, <u>Inc.</u> develops, manufactures and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on <u>hyaluronic acid</u> (<u>HA</u>), a naturally occurring, biocompatible polymer found throughout the body. Anika's products range from orthopedic/joint health solutions led by <u>ORTHOVISC</u>®, a treatment for osteoarthritis of the knee; to surgical aids in the <u>ophthalmic</u> and <u>anti-adhesion</u> fields. The company also offers <u>aesthetic dermal fillers</u> for the correction of facial wrinkles. Anika's Italian subsidiary, Fidia Advanced Biopolymers, S.r.I (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)further accomplishment of the company's key goals, (ii) approval and launch of MONOVISC, (iii) the timing of FDA approval, if at all, and the launch of key FAB orthobiologics products in the United States, (iv) the expansion of distribution of FAB's restorative tissue products internationally and advanced wound care products in the U.S., (v) the integration of FAB's operations, (vi) FAB's operations achieving breakeven in 2011, (vii) Anika's successfully building its ophthalmic product franchise over the long term by launching its own branded product, ANIKAVISC, and (viii) Anika's ability to achieve continued operational progress as well as growth in margins and earnings in 2011. 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) 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; (ii) 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; (iii) the cost effectiveness and efficiency of our manufacturing operations and production planning; (iv) 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; (v) future determinations by the Company to allocate resources to products and in directions not presently contemplated, or (vi) 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 longterm 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 Condensed Consolidated Statements of Operations

	Three Month December 3		Year Ended December 31,						
	2010	2009	2010	2009					
Product revenue Licensing,	\$14,193,352	\$9,943,938	\$52,735,730	\$37,320,906					
milestone and contract revenue	528,140	675,000	2,820,864	2,814,798					
Total revenue	14,721,492	10,618,938	55,556,593	40,135,704					
Operating expenses:									
Cost of product revenue	6,702,674	3,613,027	23,826,604	13,670,228					
Research & development	1,387,713	1,318,849	6,874,633	8,181,532					
Selling, general & administrative Total operating	4,152,895	4,083,681	17,317,671	12,697,205					

expenses Income from operations	12,243,282	9,015,557	48,018,907	34,548,965					
	2,478,210	1,603,381	7,537,685	5,586,739					
Interest income (expense), net	(45,524) (30,442) (194,620) (74,480)					
Income before income taxes	2,432,685	1,572,939	7,343,067	5,512,259					
Provision for income taxes	1,081,986	875,793	3,027,071	1,824,692					
Net income	\$1,350,701	\$697,146	\$4,315,995	\$3,687,567					
Basic net income per share:									
Net income Basic weighted	\$0.11	\$0.06	\$0.34	\$0.32					
average common shares outstanding Diluted net income per share:	12,641,394	11,384,949	12,624,495	11,386,989					
Net income Diluted weighted average common shares outstanding	\$0.10	\$0.06	\$0.32	\$0.32					
	13,672,245	11,548,079	13,646,533	11,562,304					

Anika Therapeutics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets

ASSETS	December 31, 2010	December 31, 2009
Current assets:		
Cash and cash equivalents	\$28,201,932	\$24,426,990
Short-term investments		
Accounts receivable, net of reserves of		
\$30,000 at December 31,	14,819,868	11,778,743
2010 and \$29,261 at December 31, 2009		
Inventories	8,949,745	8,547,339
Current portion deferred income taxes	2,065,517	2,228,291
Prepaid expenses and other	2,360,182	2,892,858
Total current assets	56,397,245	49,874,221
Property and equipment, at cost	49,696,989	47,172,403
Less: accumulated depreciation	(12,715,595) (11,424,788)
·	36,981,394	35,747,615
Long-term deposits and other	384,988	413,228
Intangible assets, net	25,764,185	29,975,451
Deferred income taxes	392,005	3,506,362
Goodwill	9,091,960	
Total Assets		\$129,475,885
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LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$9,694,355	\$6,354,761
Accrued expenses	5,375,584	5,816,170
Deferred revenue	2,700,000	2,751,467
Current portion of long-term debt	1,600,000	1,600,000
carrent portion or long term debt	1,000,000	1,000,000

Total current liabilities Other long-term liabilities Long-term deferred revenue Deferred tax liability	19,369,939 1,560,205 5,399,995 6,291,490	16,522,398 1,775,386 8,099,996 8,134,603
Long-term debt Commitments and contingencies (Note 9)	11,200,000	12,800,000
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no		
shares issued and outstanding at December 31, 2010 and December 31, 2009	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized,		
13,482,384 shares issued and outstanding at December 31, 2010 and 13,418,772 shares issued and outstanding at December 31, 2009	134,823	134,188
Additional paid-in-capital	61,817,558	60,539,768
Accumulated currency translation adjustment	(2,547,776)	-
Retained earnings	25,785,541	21,469,546
Total stockholders' equity	85,190,146	82,143,502
Total Liabilities and Stockholders' Equity	\$129,011,776	\$129,475,885

Anika Therapeutics, Inc. and Subsidiaries Supplemental Financial Data

Revenue by Product Line and Product Gross Margin

	Quarter Ended December 31,				Year Ended December 31,									
	2010	%		2009	%		2010	(%		2009		%	
Orthobiologics	8,419,447	59	%	6,025,469	61	%	30,741,305	į	58	%	22,879,899		61	%
Dermal	1,161,764	8	%	709,633	7	%	3,564,616	-	7	%	1,471,165		4	%
Ophthalmic surgery	3,202,936	23	%	2,741,843	28	%	11,971,787	2	23	%	10,573,915		28	%
Surgical	908,574	6	%	26,155	0	%	3,883,444	-	7	%	121,445		0	%
Veterinary	500,631	4	%	440,838	4	%	2,574,578	į	5	%	2,274,482		6	%
Total Product Revenue	\$14,193,352	2 100)%	\$9,943,938	100) %	\$52,735,730		100)%\$	37,320,906		100) %
Product gross profit	\$7,490,678			\$6,330,911			\$28,909,126				\$23,650,678			
Product gross margin	53	%		64 %			55	%			63	%		
	Quarter Ended December 31,			Year Ended December 31,										
	2010	%		2009	%		2010		%		2009		%	
Geographic Location:														
United States	\$9,262,613	65		\$7,500,601	75	%	\$35,579,636		67	%	\$27,284,346			
Europe	3,701,054	26	%	1,774,106	18	%	12,890,080		25	%	6,648,015		18	%
Other Total Product	1,229,685	9	%	669,231	7	%	4,266,014	8	3	%	3,388,545		9	%

Revenue \$14,193,352 100% \$9,943,938 100% \$52,735,730 100% \$37,320,906 100%

SOURCE: Anika Therapeutics, Inc.

Anika Therapeutics, Inc. Charles H. Sherwood, Ph.D., CEO 781-457-9000 or Kevin W. Quinlan, CFO 781-457-9000

https://ir.anika.com/Anika-Therapeutics-Reports-39-Total-Revenue-Growth-in-Fourth-Quarter-2010