

Anika Therapeutics Reports Record Revenue for 2008

BEDFORD, Mass. --(BUSINESS WIRE)--Mar. 5, 2009-- <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 record revenue for the year ending December 31, 2008.

During the fourth quarter Anika continued to strengthen its global position in joint health therapies with the domestic and international expansion of its flagship joint health product, ORTHOVISC®, and the completion of enrollment for its U.S. clinical study of MONOVISC™, Anika's single-injection osteoarthritis product. The Company also continued to invest in its future growth through its new manufacturing facility and product development initiatives.

Revenue

Anika reported product revenue of \$8,285,000 for the fourth quarter of 2008 compared with \$7,916,000 in the same period last year. For the year ended December 31, 2008, product revenue increased to \$33,055,000, compared with \$26,905,000 for full year 2007. The increase in product revenue for the quarter and the year was primarily attributable to strong sales of ORTHOVISC in the U.S. as well as sales of MONOVISC in Europe.

Total revenue for the fourth quarter of 2008 was \$8,966,000, compared with \$9,627,000 in the fourth quarter of 2007. Revenue for the fourth quarter of 2007 included \$1.2 million in revenue related to the Company's termination settlement with Galderma. For the year ended December 31, 2008, total revenue was a record \$35,780,000, compared with \$30,830,000 in 2007.

Product Gross Margin

Product gross margin for the fourth quarter of 2008 increased to 66% from 59% in last year's fourth quarter. Product gross margin for the year ended December 31, 2008 was 60% versus 56% for full year 2007. The quarter and full year improvements in gross margins were due primarily to unit growth and strong worldwide ORTHOVISC revenue, as well as the impact of sales from new products.

Other Operating Expenses

Research and development expense for the fourth quarter of 2008 increased to \$2,445,000 compared with \$1,395,000 for the same period last year. Research and development expense for the year ended December 31, 2008 increased to \$7,399,000 compared with \$4,365,000 for full year 2007. The quarter and full-year increases were primarily due to clinical trials in the U.S. and Europe for MONOVISC, manufacturing scale-up activities for ELEVESS and MONOVISC, and development activities in joint health products.

Selling, general and administrative expense for the fourth quarter of 2008 decreased to \$2,450,000 from \$2,885,000 for the same period last year, primarily due to unusually high legal, recruiting and consulting expenses in the fourth quarter of 2007. Selling, general and administrative expense for the year ended December 31, 2008 increased to \$10,965,000 from \$7,997,000 for full year 2007. The increase was due to the following three factors: 1) increased personnel costs and marketing expenses in connection with the Company's joint health franchise; 2) higher costs at Anika's Bedford facility due to a full year of occupancy and lease payments in 2008 versus only a partial year of payments and occupancy for 2007; and 3) higher year-over-year professional costs related to strategic and other corporate projects.

Net Income

Net income for the fourth quarter of 2008 was \$1,095,000, or \$0.10 per diluted share, compared with \$1,673,000, or \$0.15 per diluted share, for the same period last year. Net income for the year ended December 31, 2008 was \$3,629,000, or \$0.32 per diluted share, compared with \$6,035,000, or \$0.53 per diluted share, in 2007. The decrease in net income in both the fourth quarter and full year periods

was due to higher operating expenses, as well as lower interest income.

Other

Anika's cash, cash equivalents and short-term investments at December 31, 2008 were \$43,194,000 compared with \$39,405,000 at December 31, 2007. The increase was a result of the final drawdown in the fourth quarter of 2008 under the Company's line-of-credit, partly offset by lower accounts payable.

Management Commentary

"Anika made excellent financial and operational progress in 2008," said Charles H. Sherwood, Ph.D., Anika's president and chief executive officer. "We completed our sixth-consecutive profitable year, grew product revenue by 23 %, and delivered record ORTHOVISC product revenue. During the year, we introduced two new products to the European market, including MONOVISC, our single-injection osteoarthritis product, and ORTHOVISC mini, our hyaluronic acid-based osteoarthritis treatment specifically targeted to treat smaller joints. We also completed enrollment of our U.S. pivotal clinical trial for MONOVISC and received positive six-month data from our ongoing trial in Europe. One of the key achievements of the year was the progress we made on our new manufacturing facility, which will provide us with much-needed capacity as we capitalize on expected demand for our new products."

"We concluded a successful 2008 with another quarter of strong operating performance," said Sherwood. "We achieved record U.S. sales in the fourth quarter for our ORTHOVISC product line and achieved our highest-ever annual product gross margin at 60% for the year. We also expanded the geographic reach of our joint-health franchise with distributors in Europe, the Middle East and Southeast Asia."

"We are excited about our prospects in 2009 and beyond," said Sherwood. "We are continuing to gain market share for our joint health products and expect this trend to continue both domestically and abroad. In addition to continuing to grow sales of ORTHOVISC, we also plan to increase the market penetration of MONOVISC and ORTHOVISC mini in Europe, and file for marketing approval for MONOVISC in the U.S. Another <u>pipeline</u> milestone we expect to achieve this year is submitting a CE Mark application for CINGAL™, our new single injection joint health product with an active therapeutic molecule for pain relief. We also are optimistic about the long-term prospects for <u>ELEVESS</u>, our HA-based soft-tissue filler for facial wrinkles and scar remediation, and plan to expand distribution for this product over the balance of this year. Finally, by the end of 2009 we expect to begin manufacturing at our new state-of-the-art facility. We look forward to 2009 with confidence in our product portfolio and expect good revenue growth and improved profitability."

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights and outlook on Friday, March 6, 2008, 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 866-543-6407 (International callers dial 617-213-8898) and use the passcode 40329649. 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., <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 (HA)</u>, a naturally occurring, biocompatible polymer found throughout the body. Anika's products include <u>ORTHOVISC</u>®, a treatment for osteoarthritis of the knee available internationally and marketed in the U.S. by DePuy Mitek; <u>HYVISC</u>®, a treatment for equine osteoarthritis marketed in the U.S. by Boehringer Ingelheim Vetmedica, Inc.; the <u>ELEVESS™</u> family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation; <u>AMVISC</u>®, <u>AMVISC</u>® <u>Plus</u>, <u>STAARVISC</u>™-<u>II and Shellgel</u>™ injectable viscoelastic HA products for ophthalmic surgery; <u>INCERT</u>®, an HA-based anti-adhesive for surgical applications; <u>ORTHOVISC</u>® <u>mini</u> a treatment for osteoarthritis targeting small joints and available in Europe; <u>MONOVISC</u>™ 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 expectation of gaining market share for its joint health products both domestically and abroad, (ii) its plans to increase the market penetration of MONOVISC and ORTHOVISC mini in Europe, and file for marketing approval for MONOVISC in the U.S., (iii), Anika's expectation to submit a CE Mark application for CINGAL™, (iv) its plans to expand distribution for ELEVESS over the balance of this year, and (v) its expectation to begin manufacturing at the new state-of-theart facility in 2009. 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 license ELEVESS to a new distribution partner on terms favorable to the company, if at all; (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 and/or FDA approval, and/or 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 distribution of MONOVISC in Europe. 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 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. There can be no assurance that the company will license ELEVESS to a new distribution partner on terms favorable to the company or at all, or that the company's business won't be materially impacted by the FDA warning letter or our ability to satisfactorily resolve the issues presented therein. 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 each of the company's Annual Report on Form 10-K for the year ended December 31, 2007 and on Form 10-Q for the period ended September 30, 2008, 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 Ende	ed	Twelve Months Ended				
	December 3	l,	December 31,				
	2008	2007	2008	2007			
Product revenue	\$8,284,557	\$7,915,967	\$33,054,787	\$26,905,100			
Licensing, milestone and contract revenue	681,247	1,710,866	2,725,000	3,924,721			
Total revenue	8,965,804	9,626,833	35,779,787	30,829,821			

Operating expenses:

Cost of product revenue	2,822,930	3,225,979	13,188,516	11,880,989
revenue Research & development	2,444,529	1,395,402	7,399,049	4,364,620
Selling, general & administrative	2,449,721	2,884,634	10,965,493	7,996,781
Total operating expenses	7,717,180	7,506,015	31,553,058	24,242,390
Income from operations	1,248,624	2,120,818	4,226,729	6,587,431
Interest income, net	20,745	408,041	498,512	2,100,663
Income before income taxes	1,269,369	2,528,859	4,725,241	8,688,094
Provision for income taxes	174,864	855,463	1,096,046	2,652,840
Net income Basic net income per share:	\$1,094,505	\$1,673,396	\$3,629,195	\$6,035,254
Net income Basic weighted	\$0.10	\$0.15	\$0.32	\$0.55
average common shares outstanding Diluted net income per share:	11,352,383	11,177,521	11,308,124	11,059,582
Net income Diluted weighted	\$0.10	\$0.15	\$0.32	\$0.53
average common shares outstanding	11,456,691	11,511,862	11,460,801	11,453,600

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

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$43,193,655	\$35,903,569
Short-term investments	_	3,501,974
Accounts receivable, net	5,418,421	5,795,973
Inventories	5,519,754	4,390,118
Current portion of deferred income taxes	1,235,364	1,657,007
Prepaid expenses and other	463,284	1,194,081
Total current assets	55,830,478	52,442,722
Property and equipment, at cost	42,436,827	28,101,422
Less: accumulated depreciation	(10,190,144)	(8,731,706)
	32,246,683	19,369,716
Long-term deposits and other	506,787	433,081
Intangible asset, net	936,275	995,098
Deferred income taxes	6,300,665	6,256,067
Total Assets	\$95,820,888	\$79,496,684

LIABILITIES AND STOCKHOLDERS' EQUITY

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Deferred revenue, current	2,732,393	2,806,778
Long-term debt, current	1,600,000	_
Income taxes payable	_	203,954
Other long-term liabilities	831,051	398,365
Long-term deferred revenue	10,800,001	13,500,001
Long-term debt	14,400,000	-
Total liabilities	35,064,004	24,535,727
Stockholders' equity		
Preferred stock	_	_
Common stock	113,776	112,233
Additional paid-in-capital	42,861,229	40,695,940
Retained earnings	17,781,979	14,152,784
Total stockholders' equity	60,756,984	54,960,957
Total Liabilities and Stockholders' Equity	\$95,820,988	\$79,496,684

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

Product Gross Margin and Revenue by Product Line

	Quarter Ended December 31,						Twelve Months Ended							
								December 31,						
	2008	%	Ttl	2007		% 7	Γtl	2008	% -	Γtl	2007		% T	ΓtΙ
Joint Health	\$5,143,768	6	2 %	\$4,707,74	2	59	%	\$18,707,669	57	%	\$13,602,49	4	51	%
Ophthalmic	2,394,631	2	9 %	2,448,54	5	31	%	10,678,615	32	%	10,517,15	6	39	%
Veterinary	600,880	7	%	688,028		9	%	3,028,450	9	%	2,370,898		9	%
Aesthetics	105,903	2	%	_		0	%	505,273	2	%	224,220		1	%
Other	39,375	0	%	71,652		1	%	134,780	0	%	190,332		0	%
	\$8,284,557	1	00%	\$7,915,96	7	100) %	\$33,054,787	100) %	\$26,905,10	0	100)%
Product gross profit	\$5,461,627			\$4,689,98	8			\$19,866,271			\$15,024,11	1		
Product gross margin	66	%		59	%			60	%		56	%		

Product Revenue by Geography

Quarter Ended			Twelve Months	Ended		
	December 31	,	December 31,			
	2008	% Ttl 2007	% Ttl 2008	% Ttl 2007	% Ttl	
Domestic	\$5,884,332	71 % \$5,858,105	74 % \$24,064,512	73 % \$20,034,764	74 %	
Internationa	al 2,400,225	29 % 2,057,862	26 % 8,990,275	27 % 6,870,336	26 %	
	\$8,284,557	100% \$7,915,967	100 % \$33,054,787	100% \$26,905,100	100%	

Source: Anika Therapeutics, Inc.

Anika Therapeutics, Inc.

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https://ir.anika.com/Anika-Therapeutics-Reports-Record-Revenue-for-2008