

Anika Therapeutics Reports First Quarter 2009 Results

BEDFORD, Mass. --(BUSINESS WIRE)--Apr. 29, 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 financial results for the quarter ending March 31, 2009.

Key Highlights

During the first 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®;
- Increased both total revenues and product revenues by 8%; and
- Grew joint health revenues by 25%.

Revenue

Anika's product revenue increased by 8% to \$8,519,000 for the first quarter of 2009, compared with \$7,868,000 in the same period last year. The increase in product revenue for the quarter was primarily attributable to strong domestic and international sales of the Company's ORTHOVISC product line, as well as gains from MONOVISC sales.

Total revenue for the first quarter of 2009 increased 8% to \$9,200,000 from \$8,549,000 in the first quarter of 2008.

Product Gross Margin

Product gross margin for the first quarter of 2009 increased to 62% from 59% in last year's first quarter. The improvement in gross margins was due primarily to the growth in joint health product revenue, resulting in a more favorable product mix.

Other Operating Expenses

Research and development expense increased to \$2,194,000 compared with \$1,508,000 in the same period last year, primarily due to the U.S. clinical trials for MONOVISC, manufacturing validation activities at the Bedford facility, and other development activities in joint health and aesthetics. Selling, general and administrative expense was \$3,035,000 compared with \$3,069,000 in the same period last year.

Net Income

Net income for the first quarter of 2009 was \$523,000, or \$0.05 per diluted share, compared with \$618,000, or \$0.05 per diluted share, for the same period last year. The decrease in net income in the first quarter was due to the current lower interest rate environment.

Other

Anika's cash and cash equivalents at March 31, 2009 were \$40,427,000 compared with \$43,194,000 at December 31, 2008. The decrease in cash was due to greater working capital needs, and planned capital expenditures, as well as a payment for the Company's debt obligation related to the new facility.

Management Commentary

"Anika began the year with another quarter of solid revenue growth, driven primarily by our joint health franchise," said Charles H. Sherwood, Ph.D., Anika's president and chief executive officer. "Revenues for joint

health were up by 25 percent with strong domestic and international contributions."

"After having completed the enrollment for our U.S. pivotal clinical trial for Anika's new single-injection osteoarthritis treatment, MONOVISC, and as we did with ORTHOVISC, we initiated a follow-up reinjection study for the product," said Sherwood. "In this study, we plan to re-treat approximately two-thirds of the initial patients in order to demonstrate the safety of repeat injections. We are on-track to file for marketing approval for MONOVISC in the U.S. by the end of this year."

"Looking forward, we plan to continue to capitalize on strong trends in joint health as we broaden our presence through an increasing number of distributors and an expanding suite of innovative products," said Sherwood. "Even in the short term, we believe that patients will turn to ORTHOVISC and other HA procedures to postpone expensive and debilitating knee replacement surgery during this recessionary period. We continue to look forward to generating revenue growth and improved income in 2009."

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights and outlook on Thursday, April 30, 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 866-788-0542 (International callers dial 857-350-1680) and use the passcode 37421541. 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</u> (<u>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 company's expectations concerning its MONOVISC product, including the U.S. trial and the filing of a PMA (ii) expectations for ORTHOVISC growth during the recession (iii) statements concerning leveraging investments into new products, (iv) statements concerning revenue and income performance in 2009, and (v) statements regarding capitalizing on strong trends in joint health as the Company broadens its presence through an increasing number of distributors and an expanding suite of innovative products. 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; (vi) 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 Europe, 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 (including its distributor in Turkey) 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, including non-reimbursement of ORTHOVISC in Turkey, 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. Certain other factors that might cause the company's actual results to differ materially from those in the forwardlooking 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, 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 March 31,	
	2009	2008
Product revenue	\$8,519,073	\$7,867,529
Licensing, milestone and contract revenue	681,251	681,250
Total revenue	9,200,324	8,548,779
Operating expenses:		
Cost of product revenue	3,211,666	3,216,070
Research & development	2,194,308	1,508,340
Selling, general & administrative	3,034,982	3,068,616
Total operating expenses	8,440,956	7,793,026
Income from operations	759,368	755,753
Interest income, net	1,440	189,406
Income before income taxes	760,808	945,159
Provision for income taxes	238,088	327,601
Net income	\$522,720	\$617,558
Basic net income per share (a):		
Net income	\$0.05	\$0.05
Basic weighted average common shares outstanding	11,366,545	11,225,282
Diluted net income per share (a):		
Net income	\$0.05	\$0.05
Diluted weighted average common shares outstanding	11,496,518	11,612,720

(a) On January 1, 2009, the company adopted FSP EITF 03-6-1 concerning the calculation of earnings per share ("EPS"). The adoption is retroactive to all periods presented and reduced three months ended March 31, 2008 basic EPS from \$0.06 to \$0.05.

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ACCETC	March 31, 2009	December 31, 2008
ASSETS Current assets: Cash and cash equivalents Accounts receivable, net Inventories Current portion of deferred income taxes Prepaid expenses and other Total current assets Property and equipment, at cost Less: accumulated depreciation	\$40,426,703 6,483,017 5,897,332 1,235,364 858,931 54,901,347 43,481,029 (10,508,898) 32,972,131	\$43,193,655 5,418,421 5,519,754 1,235,364 463,284 55,830,478 42,436,827 (10,190,144 32,246,683
Long-term deposits and other Intangible asset, net Deferred income taxes Total Assets	357,603 921,569 6,213,980 \$95,366,630	506,787 936,275 6,300,665 \$95,820,888
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable Accrued expenses Deferred revenue, current Long-term debt, current Income taxes payable Other long-term liabilities Long-term deferred revenue	\$2,036,244 2,612,902 2,732,018 1,600,000 43,544 891,954 10,124,996	\$2,375,340 2,325,219 2,732,293 1,600,000 — 831,051 10,800,001
Long-term debt Total liabilities Stockholders' equity Preferred stock Common stock Additional paid-in-capital Retained earnings	14,000,000 34,041,658 — 114,359 42,905,914 18,304,699	14,400,000 35,063,904 — 113,776 42,861,229 17,781,979
Total stockholders' equity Total Liabilities and Stockholders' Equity	61,324,972 \$95,366,630	60,756,984 \$95,820,888

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

Product Gross Margin and Revenue by Product Line

	Quarter Ended March 31,			
	2009	% Ttl	2008	% Ttl
Joint Health	\$ 5,149,642	60%	\$ 4,122,180	53%
Ophthalmic	2,645,252	31%	3,018,671	38%
Veterinary	637,335	8%	700,623	9%
Aesthetics	50,094	1%	3,000	0%
Other	36,750	0%	23,055	0%
	\$ 8,519,073	100%	\$ 7,867,529	100%

Product gross profit \$25,307,407

\$4,651,459

Product Revenue by Geography

Quarter Ended March 31,

2009 % Ttl 2008 % Ttl Domestic \$ 6,135,564 72% \$ 6,154,111 78% 22% International 2,383,509 28% 1,713,418 \$ 8,519,073 100% \$ 7,867,529 100%

Source: Anika Therapeutics, Inc.

Anika Therapeutics, Inc.

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or

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https://ir.anika.com/Anika-Therapeutics-Reports-First-Quarter-2009-Results