

Anika Therapeutics Reports First-Quarter 2015 Financial Results

Product Revenue Grows 8% to \$15.5 Million U.S. Monovisc® Reaching 3% Market Share in Q1 2015 Company Continues Clinical, Regulatory and Commercial Advancements

BEDFORD, Mass.--(BUSINESS WIRE)-- <u>Anika Therapeutics, Inc.</u> (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 March 31, 2015.

Management Commentary

"Our strong momentum continued throughout the first quarter as we made excellent clinical, regulatory, and commercial progress across our product franchises," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "From a financial perspective, we delivered solid first-quarter results, achieving total revenue of \$15.5 million and net income of \$3.5 million.

"End user demand continues to be strong for our orthobiologics products. Monovisc end user sales increased 41% sequentially from the fourth quarter of 2014 and reached close to 3% market share exiting the first quarter. This demonstrates that the product's unique J-Code, which became effective on January 1, 2015, is having the positive effect that we expected. Our growth target for Monovisc in the U.S. is to more than double our year-end 2014 market share by reaching a minimum share of 5% by the end of 2015.

"Cingal[®] continues to advance toward commercialization," said Dr. Sherwood. "In Q1, we submitted a PMA application with the FDA ahead of schedule on the strength of our pivotal Phase III study. The study met all primary and secondary endpoints and unequivocally demonstrated the strong clinical benefit of Cingal. We recently completed the enrollment of an open-label, follow-up study, and we expect to report safety data in the third quarter of this year.

"In April, we achieved an important milestone when our lead wound care product, Hyalomatrix, became eligible for reimbursement as a skin substitute by the Centers for Medicare and Medicaid Services in 11 states and Washington D.C. Our distribution partner, Medline Industries, Inc., continues to work closely with leading reimbursement experts to expand this coverage in the U.S.

"Hyalofast® is our lead regenerative medicine offering and functions as an innovative cartilage regeneration product with unique characteristics that should enable us to gain a share of a growing market. In April, we filed an Investigational Device Exemption, or IDE, with the FDA to conduct a pivotal Phase III clinical trial for Hyalofast. We are expecting to commence the trial later this year. In addition, we remain focused on developing our regenerative medicine pipeline and we see opportunities to develop products for other soft tissue repair applications.

"We have tremendous growth opportunities with our commercialized products, and we are making excellent progress with additional innovative pipeline products with great potential in large markets," concluded Dr. Sherwood.

Revenue

Anika's total revenue for the first quarter of 2015 was \$15.5 million, compared with \$34.0 million in the first quarter of 2014. First-quarter 2014 total revenue included \$19.7 million in milestone and contract revenue associated with Anika's U.S. license agreement for Monovisc. Anika's product revenue for the first quarter of 2015 increased to \$15.5 million, compared with \$14.4 million in the first quarter of 2014.

Product Gross Margin and Operating Expenses

Product gross margin for the first quarter of 2015 improved to 72% from 70% in the first quarter of 2014. The increase was primarily due to a more favorable revenue mix. Total operating expenses for the first quarter of 2015 were \$10.0 million, essentially flat year-over-year. Research and development expenses decreased 8% from the first quarter of 2014, reflecting lower costs from the Cingal clinical trial, which was completed in Q4 2014. Selling, general, and administrative expenses for the first quarter increased 3% from the year-earlier quarter due to higher external professional fees and performance-based stock compensation expenses.

Operating and Net Income

Operating income for the first quarter of 2015 was \$5.5 million, down 77% year-over-year. Net income for the first quarter was \$3.5 million, or \$0.23 per diluted share, compared with \$15.0 million, or \$0.97 per diluted share, a year ago. The Q1 2014 net income included milestone and contract revenue of \$19.7 million, or \$0.78 per diluted share.

Cash and Investments

Anika's cash and investments at March 31, 2015 increased to \$112.3 million from \$106.9 million at December 31, 2014. This \$5.4 million increase was driven primarily by continued operating income and proceeds from stock options exercises during the period.

Conference Call Information

Anika will hold a conference call to discuss its financial results, business highlights, and financial outlook tomorrow, Wednesday, April 29 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 855-468-0611 (international callers dial 484-756-4332). In addition, the call will be available through a live audio webcast in the <u>"Investor Relations"</u> section of Anika's website, <u>www.anikatherapeutics.com</u>. An accompanying slide presentation also may be accessed via the Anika Therapeutics website. The call will be archived and accessible on the same website shortly after its conclusion.

About Anika Therapeutics, Inc.

Headquartered in Bedford, Mass., <u>Anika Therapeutics, 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>® and <u>Monovisc</u>, treatments for osteoarthritis, to surgical aids in the <u>anti-adhesion</u> and <u>ophthalmic</u> fields. The Company also offers <u>aesthetic dermal fillers</u> for the correction of facial wrinkles. Anika's Italian subsidiary, Anika Therapeutics S.r.l., provides complementary HA products in orthopedic/joint health and anti-adhesion, as well as therapeutics in areas such as advanced wound treatment and ear, nose and throat care. Its regenerative technology advances Anika's vision to offer therapeutic products and medical solutions that go beyond pain relief to protect and restore damaged tissue.

The statements made in the second, third, fourth, fifth, and sixth paragraphs under the heading "Management Commentary" 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, those relating to the Company's expectations related to market share expansion of Monovisc in the United States, including the effect of the Company's unique I-Code on those expectations, the timing, results, and availability of clinical data for the Cingal follow-up study, the Company's expectations related to the expansion of Hyalomatrix reimbursement coverage in the United States, the Company's expectations related to Hyalofast product development and commercialization, and the Company's expectations related to its regenerative medicine pipeline and commercial opportunities. 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 pre-clinical or clinical data to support domestic and international pre-market approval applications or 510(k) applications, or timely file and receive FDA or other regulatory approvals or clearances of its products, or that such approvals will not be obtained in a timely manner or without the need for additional clinical trials, other testing or regulatory submissions, as applicable; (ii) the Company's research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (iii) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations and production planning; (iv) the strength of the economies in which the Company operate 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; (vi) the Company's ability to successfully complete its commercialization plan for Monovisc, and its other products, in the U.S. and abroad; (vii) the Company's ability to provide an adequate and timely supply of its products to its customers; (viii) the Company's ability to continue to successfully manage Anika Therapeutics S.r.l.'s business; and (ix) the Company's ability to achieve its growth targets.

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

(unaudited)	Three Months Ended March		
	31,	2014	
Product revenue	2015 ¢15 514 692	2014 ¢14 251 405	
Licensing, milestone and contract revenue	\$15,514,682 5,642	\$14,351,405 19,658,882	
Total revenue	15,520,324		
lotal revenue	13,320,324	54,010,207	
Operating expenses:			
Cost of product revenue	4,313,440	4,361,019	
Research & development	2,097,762	2,287,715	
Selling, general & administrative	3,604,661	3,490,985	
Total operating expenses	10,015,863		
Income from operations	5,504,461	23,870,568	
Interest income, net	23,723	467	
Income before income taxes	5,528,184	23,871,035	
Provision for income taxes	2,012,627	8,840,782	
Net income	\$3,515,557	\$15,030,253	
Basic net income per share:			
Net income	\$0.24	\$1.04	
Basic weighted average common shares	14,905,322	14,461,367	
outstanding	14,505,522	14,401,507	
Diluted net income per share:			
Net income	\$0.23	\$0.97	
Diluted weighted average common shares outstanding	15,330,054	15,499,447	

Anika Therapeutics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets

ASSETS	March 31, 2015	December 31, 2014
Current assets:		
Cash and cash equivalents	\$99,802,205	\$100,155,864
Investments	12,500,000	6,750,000
Accounts receivable, net of reserves		
of \$130,877 and \$146,618 at	16,025,212	17.152.028
March 31, 2015 and December		_///
31,2014, respectively		
Inventories	12,515,787	12,406,776
Prepaid income taxes	2,555,436	412,301
Current portion deferred income taxes	1,487,846	1,188,768
Prepaid expenses and other	1,034,597	959,305
Total current assets	145,921,083	139,025,042
Property and equipment, at cost	53,666,109	53,619,589
Less: accumulated depreciation	(22,476,104)	(21,950,706)
	31,190,005	31,668,883
Long-term deposits and other	69,010	69,042

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LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Accounts payable Accrued expenses Deferred revenue Total current liabilities Other long-term liabilities Long-term deferred revenue Deferred tax liability Commitments and contingencies Stockholders' equity: Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	\$1,774,812 4,242,979 139,535 6,157,326 829,302 85,510 8,797,200	\$1,201,226 4,747,526 24,510 5,973,262 893,935 102,192 8,929,890
Common stock, \$.01 par value; 30,000,000 shares authorized, 15,003,069 and 14,851,703 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively Additional paid-in-capital	150,030 79,990,228	148,517 77,539,699
Accumulated other comprehensive	(6,743,928)	(4,494,800)
loss Retained earnings Total stockholders' equity Total Liabilities and Stockholders' Equity	(0,743,928) 108,419,238 181,815,568 \$197,684,906	(4,494,800) 104,903,681 178,097,097 \$193,996,376

Anika Therapeutics, Inc. and Subsidiaries Supplemental Financial Data

Revenue by Product Line and Product Gross Margin (unaudited)

	Quarter Ended March 31,						
	2015	%		2014		%	
Orthobiologics	\$11,972,500	77	%	\$11,572,150		81	%
Dermal	416,183	3	%	188,651		1	%
Surgical	1,389,595	9	%	1,752,020		12	%
Ophthalmic	504,472	3	%	208,584		2	%
Veterinary	1,231,932	8	%	630,000		4	%
Total Product Revenue	\$15,514,682	10	0 %	\$14,351,405		100) %
Product gross profit	\$11,201,242			\$9,990,386			
Product gross margin	72 🦻	6		70	%		

Total Product Revenue by Geographic Region (unaudited)

	Quarter Ended March 31,			
	2015	%	2014	%
Georgraphic Location:				
United States	\$12,591,189	81 %	\$11,881,039	83 %
Europe	1,986,324	13 %	1,695,816	12 %
Other	937,169	6 %	774,550	5 %
Total Revenue	\$15,514,682	100~%	\$14,351,405	100 %

Anika Therapeutics, Inc. Charles H. Sherwood, Ph.D., President and CEO or Sylvia Cheung, CFO 781-457-9000

Source: Anika Therapeutics, Inc.

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