

Anika Reports Third Quarter 2016 Financial Results

Worldwide Orthobiologics Revenue Increases 10% Year-over-Year Diluted Earnings Per Share Increases to \$0.59

BEDFORD, Mass.--(BUSINESS WIRE)-- <u>Anika Therapeutics, Inc.</u> (NASDAQ: ANIK), a global, integrated orthopedic medicines company specializing in therapeutics based on its proprietary <u>hyaluronic acid ("HA") technology</u>, today reported financial results for the third quarter ended September 30, 2016, along with business progress in the period.

"We continued to deliver solid financial results in the third quarter, while expanding globally and advancing our deep and differentiated pipeline to drive sustained growth," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "Last quarter, we had a productive meeting with the FDA regarding the CINGAL regulatory submission and continue to gain alignment on additional clinical and non-clinical work required to bring this important treatment to the U.S. Our confidence in the future success of CINGAL in the U.S. has been reaffirmed by how well CINGAL has been received by physicians in Canada and Europe, where we recently launched. We are well-positioned to achieve our operational and financial objectives for 2016 and to create significant near- and long-term value for patients and shareholders."

Third Quarter Financial Results

- Total revenue for the third quarter of 2016 increased 9% to \$25.8 million, compared to \$23.7 million for the third quarter of 2015.
- Worldwide Orthobiologics revenue grew 10% year-over-year in the third quarter of 2016. MONOVISC revenue increased 33% year-over-year in the third quarter of 2016, and it was the Company's main revenue growth driver during the period.
- International Orthobiologics revenue grew 27% year-over-year in the first nine months of 2016 as a result of the Company's global commercial expansion efforts. Domestically, we believe ORTHOVISC maintained its position as the leading multiple-injection product while MONOVISC continued to hold the number two position in the single-injection segment.
- Total operating expenses for the third quarter of 2016 were \$12.1 million, compared to \$10.5 million for the third quarter of 2015, commensurate with the Company's growth in revenue, increased commercial efforts, and active pipeline.
- Net income for the third quarter of 2016 increased \$0.6 million to \$9.0 million, or \$0.59 per diluted share, compared to \$8.4 million, or \$0.55 per diluted share, for the third quarter of 2015.

Recent Business Highlights

The Company made key commercial, operational, pipeline, and financial advancements, including:

- Meeting with the U.S. Food and Drug Administration (FDA) in late September about the New Drug Application (NDA) for CINGAL, during which the Company and FDA aligned on one additional Phase III clinical trial to supplement the strong stable of existing pivotal data.
- Advancing its product pipeline with continued progress on enrolling patients in the FastTRACK Phase III
 HYALOFAST Study for cartilage repair, as well as the Phase III MONOVISC study for the treatment of
 osteoarthritis pain in the hip.
- Showcasing data from four recent studies evaluating the clinical utility of our HA-based bioscaffold, HYALOFAST, at the 13th World Congress of the International Cartilage Repair Society (ICRS).
- Completing the Company's \$25 million accelerated share repurchase program, with a total of 531,067 shares repurchased by Anika.
- Progressing with the consolidation of the Company's global manufacturing operations at Anika's Bedford, Mass. global headquarters.

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights tomorrow, Thursday, October 27th at 9:00 am ET. The conference call can be accessed by dialing 1-855-468-0611 (toll-free domestic) or 1-484-756-4332 (international). A live audio webcast will be available in the "Investor Relations" section of Anika's website, www.anikatherapeutics.com. An accompanying slide presentation may also be accessed via the Anika website. A replay of the webcast will be available on Anika's website approximately two hours after the completion of the event.

About Anika Therapeutics, Inc.

Anika Therapeutics, Inc. (NASDAQ: ANIK) is a global, integrated orthopedic medicines company based in Bedford, Massachusetts. Anika is committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions with clinically meaningful therapies along the continuum of care, from palliative pain management to regenerative cartilage repair. The Company has over two decades of global expertise developing, manufacturing, and commercializing more than 20 products based on its proprietary <a href="https://pys.orthopedic.org/hyaluronic.org/hya

Forward-Looking Statements

The statements made in the last sentence of the second paragraph of 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 future growth and creation of value, and the Company's ability and positioning to meet its 2016 financial and operational goals. 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, but not limited to, (i) the Company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all; (ii) the Company's ability to obtain preclinical or clinical data to support domestic and international pre-market approval applications, 510(k) applications, or new drug applications, or to timely file and receive FDA or other regulatory approvals or clearances of its products; (iii) 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; (iv) 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; (v) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations, and production planning; (vi) 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; (vii) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (viii) the Company's ability to successfully commercialize its products, in the U.S. and abroad; (ix) the Company's ability to provide an adequate and timely supply of its products to its customers; and (x) the Company's ability to achieve its growth targets. Additional factors and risks are described in the Company's periodic reports filed with the Securities and Exchange Commission (SEC), and they are available on the SEC's website at www.sec.gov. Forward-looking statements are made based on information available to the Company on the date of this press release, and the Company assumes no obligation to update the information contained in this press release.

Anika Therapeutics, Inc. and Subsidiaries Condensed Consolidated Statements of Operations (in thousands, except per share data) (unaudited)

	For the Thr Ended Sept		For the Nine Months Ended September 30,			
	2016	2015	2016	2015		
Product revenue	\$ 25,783	\$ 23,676	\$74,636	\$62,089		
Licensing, milestone and contract revenue	6	5	17	16		
Total revenue	25,789	23,681	74,653	62,105		
Operating expenses:						
Cost of product revenue Research & development	4,998 2,822	5,176 2,061	16,488 7,773	14,764 5,971		

Selling, general &	4,280	3,309	12,525	10,302
administrative Total operating expenses	12,100	10,546	36,786	31,037
Income from operations	13,689	13,135	37,867	31,068
Interest income, net	93	34	214	82
Income before income taxes	13,782	13,169	38,081	31,150
Provision for income taxes	4,830	4,789	13,619	11,435
Net income	\$ 8,952	\$8,380	\$24,462	\$19,715
Basic net income per share: Net income	\$ 0.61	\$ 0.56	\$1.66	\$1.32
Basic weighted average	,	,	,	, -
common shares outstanding	14,625	14,967	14,726	14,945
Diluted net income per share:				
Net income	\$ 0.59	\$ 0.55	\$1.61	\$1.29
Diluted weighted average common shares outstanding	15,077	15,316	15,163	15,311

Anika Therapeutics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets (in thousands, except share data and per share data) (unaudited)

ASSETS Current assets:	September 30, 2016	December 31, 2015
Cash and cash equivalents Investments Accounts receivable, net of reserves	\$98,047 22,250	\$110,707 27,751
of \$224 and \$167 at September 30, 2016 and December 31, 2015, respectively	21,833	21,652
Inventories Prepaid expenses and other current assets	18,020 924	14,938 1,385
Total current assets Property and equipment, net	161,074 51,058	176,433 40,108
Long-term deposits and other Intangible assets, net	69 11,171	69 11,656
Goodwill Total Assets	7,690 \$231,062	7,482 \$235,748
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:		
Accounts payable	\$1,949	\$8,302
Accrued expenses and other current liabilities	5,423	4,778
Income taxes payable	217	4,198
Total current liabilities	7,589	17,278
Other long-term liabilities	2,556	781
Long-term deferred revenue Deferred tax liability	59 6,315	66 6,775
Commitments and contingencies	0,313	0,773
Stockholders' equity: Preferred stock, \$.01 par value; 1,250,000 shares	5	
authorized, no shares issued and outstanding at September 30, 2016 and December 31, 2015,	- -	-

CERPARTIVE Wock, \$.01 par value; 60,000,000 and 30,000,000 shares authorized, 14,623,225 and 15,036,808 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	146	150
Additional paid-in-capital	60,374	81,685
Accumulated other comprehensive loss	(6,101)	(6,649)
Retained earnings	160,124	135,662
Total stockholders' equity	214,543	210,848
Total Liabilities and Stockholders' Equity	\$231,062	\$235,748

Anika Therapeutics, Inc. and Subsidiaries Supplemental Financial Data

Revenue by Product Line and Product Gross Margin (in thousands, except percentages) (unaudited)

	For the T Ended Se		For the Nine Months Ended September 30,									
	2016	%		2015	%		2016	%		2015	%	
Orthobiologics	\$22,428	87	%	\$20,461	86	%	\$65,319	88	%	\$51,717	83	%
Surgical	1,173	5	%	1,413	6	%	3,924	5	%	4,450	7	%
Dermal	594	2	%	412	2	%	1,558	2	%	1,132	2	%
Other	1,588	6	%	1,390	6	%	3,835	5	%	4,790	8	%
Product Revenue	\$25,783	100)%	\$23,676	100	0%	\$74,636	100) %	\$62,089	100)%
Product Gross Profit	\$20,785			\$18,500			\$58,148			\$47,325		
Product Gross Margin	81%			78%			78%			76%		

Product Revenue by Geographic Region (in thousands, except percentages) (unaudited)

	For the T Ended Se		For the Nine Months Ended September 30,									
	2016	%		2015	%		2016	%		2015	%	
Geographic Location:												
United States	\$21,126	82	%	\$19,239	82	%	\$61,032	82	%	\$51,048	82	%
Europe	2,703	10	%	1,977	8	%	8,240	11	%	6,294	10	%
Other	1,954	8	%	2,460	10	%	5,364	7	%	4,747	8	%
Product Revenue	\$25,783	100)%	\$23,676	100)%	\$74,636	100)%	\$62,089	100)%

View source version on <u>businesswire.com</u>: <u>http://www.businesswire.com/news/home/20161026006717/en/</u>

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