

Anika Reports Fourth Quarter and Full Year 2016 Financial Results

Worldwide Orthobiologics Revenue Increases 13% Year-over-Year for Fourth Quarter of 2016 Product Revenue Grows 17% for Full Year of 2016

BEDFORD, Mass.--(BUSINESS WIRE)-- <u>Anika Therapeutics</u>, <u>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 fourth quarter and full year ended December 31, 2016, along with business progress in the periods.

"Anika delivered another year of very strong growth, with 17% product revenue growth for the full year of 2016," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "We also submitted an IND application to the FDA to initiate an additional Phase III clinical trial of CINGAL, and we received CE Mark approval for ORTHOVISC-T in the fourth quarter, paving the way for our next generation of growth drivers. We expect to commence the CINGAL Phase III trial and launch ORTHOVISC-T in Europe in the first half of 2017. Our strategic objectives in 2017 are focused on global commercial expansion, pipeline advancement, infrastructure enhancements and strategic M&A to drive sustained growth and create value for patients and shareholders."

Fourth Ouarter and Full Year Financial Results

- Product revenue increased 11% for the fourth quarter of 2016, and 17% for the full year of 2016, as compared to the same periods in 2015.
- Total revenue for the fourth quarter of 2016 was \$28.7 million, compared to \$30.9 million for the fourth quarter of 2015. The decline was due to the achievement of \$5 million of contractual milestone revenue in the fourth quarter of 2015 for reaching a targeted MONOVISC U.S. end user sales threshold. Total revenue for the full year of 2016 grew 11% to \$103.4 million, compared to \$93.0 million for the full year of 2015.
- Worldwide Orthobiologics revenue increased 13% year-over-year in the fourth quarter of 2016. For the full year of 2016, worldwide Orthobiologics revenue increased 22% and MONOVISC revenue grew 54%, which was the main overall revenue growth driver.
- International Orthobiologics revenue increased 24% for the full year of 2016, due primarily to the global expansion of MONOVISC. Domestically, ORTHOVISC and MONOVISC continue to maintain a market leading position.
- Total operating expenses for the fourth quarter of 2016 were \$16.0 million, compared to \$13.8 million for the fourth quarter of 2015, commensurate with the growth in product revenue, expanded commercial efforts and active pipeline development. Total operating expenses for the full year of 2016 were \$52.8 million, compared to \$44.9 million for the full year of 2015.
- Net income for the fourth quarter of 2016 was \$8.1 million, or \$0.54 per diluted share, compared to \$11.0 million, or \$0.72 per diluted share, for the fourth quarter of 2015. Fourth quarter 2015 results reflected the favorable impact of the \$5 million of licensing, milestone and contract revenue previously discussed. Net income for the full year of 2016 increased \$1.8 million to \$32.5 million, or \$2.15 per diluted share, compared to \$30.8 million, or \$2.01 per diluted share, for the full year of 2015.

Recent Business Highlights

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

- Submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate an additional Phase III clinical trial of CINGAL.
- Receiving CE Mark approval for a treatment, which will be marketed internationally as ORTHOVISC-T, indicated to relieve pain and restore function in tendons affected by chronic lateral epicondylosis.
- 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.
- Progressing with the consolidation of the Company's global manufacturing operations at Anika's Bedford,

Massachusetts corporate headquarters.

Full Year 2017 Corporate Outlook

Looking forward to 2017, the Company expects total revenue growth to be in the mid-teen percentage range for the full year of 2017. Licensing, milestone and contract revenue is expected to be \$5 million for the year. The Company also anticipates continued headway on several key initiatives including:

- Commencement of the Phase III clinical trial of CINGAL, to supplement the strong stable of existing pivotal data.
- Launch of ORTHOVISC-T in Europe, and the initiation of a Phase III clinical trial for U.S. approval of the treatment.
- International expansion of MONOVISC and CINGAL.
- Continued progress toward full patient enrollment in the FastTRACK Phase III HYALOFAST study, with over 50% of the total patient population enrolled by the end of 2017.
- Completion of the consolidation of the Company's global manufacturing operations at Anika's Bedford, Massachusetts corporate headquarters.
- Continued progress toward the development of a direct commercialization capability in the U.S.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights tomorrow, Thursday, February 16th 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 hyaluronic acid (HA) technology. Anika's orthopedic medicine portfolio includes ORTHOVISC®, MONOVISC®, and CINGAL®, which alleviate pain and restore joint function by replenishing depleted HA, and <a href="https://hyaluronic.org/hyaluronic.o

Forward-Looking Statements

The statements made in the third and fourth sentences of the second paragraph, as well as all of the information in the section captioned "Full Year 2017 Corporate Outlook" 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 expectations regarding 2017 revenue growth, 2017 contractual milestone revenue, total 2017 operating expenses, product launches and territorial expansion for existing products, commencement of the CINGAL clinical trial, strategic objectives, including the Company's focus on strategic M&A, progression of the HYALOFAST FastTRACK clinical trial enrollment, consolidation of manufacturing operations, and progress in the development of its direct commercialization capability. 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 pre-clinical 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, 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)

Product revenue	For the Thr Ended Deco 2016 \$ 28,296		For the Year Ended December 31, 2016 2015 \$102,932 \$87,696		
Licensing, milestone and contract revenue	430	5,287	447	5,303	
Total revenue	28,726	30,894	103,379	92,999	
Operating expenses: Cost of product revenue Research & development Selling, general & administrative Total operating expenses Income from operations Interest income, net Income before income taxes Provision for income taxes Net income	7,539 2,959 5,488 15,986 12,740 49 12,789 4,704 \$8,085	6,290 3,016 4,524 13,830 17,064 39 17,103 6,061 \$11,042	24,027 10,732 18,013 52,772 50,607 263 50,870 18,323 \$32,547	21,053 8,987 14,825 44,865 48,134 120 48,254 17,496 \$30,758	
Basic net income per					
share: Net income Basic weighted average	\$ 0.56	\$ 0.74	\$2.22	\$2.06	
common shares outstanding Diluted net income per	14,538	14,965	14,682	14,934	
share: Net income	\$ 0.54	\$0.72	\$2.15	\$2.01	
Diluted weighted average common shares outstanding	14,979	15,353	15,116	15,321	

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

	December 31,	December 31,
ASSETS	2016	2015
Current assets:		
Cash and cash equivalents	\$104,261	\$110,707
Investments	20,500	27,751

Accounts receivable, net of reserves	27,598	21,652
of \$194 and \$167 at December 31, 2016 and December 31, 2015, respectively	27,590	21,032
Inventories	15,983	14,938
Prepaid expenses and other current assets	2,098	1,385
Total current assets Property and equipment, at cost	170,440 79,079	176,433 64,648
Less: accumulated depreciation	(26,783)	(24,540)
Property and equipment, net	52,296	40,108
Long-term deposits and other	69	69
Intangible assets, net	10,227	11,656
Goodwill	7,214	7,482
Total Assets	\$240,246	\$235,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,303	\$8,302
Accrued expenses and other current liabilities	6,496	4,778
Current portion of long-term debt		4.100
Income taxes payable Total current liabilities	- 8,799	4,198 17,278
Other long-term liabilities	2,078	781
Long-term deferred revenue	48	66
Deferred tax liability	6,548	6,775
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250 shares		
authorized, no shares issued and outstanding at December 31, 2016 and December 31,	-	-
2015, respectively		
Common stock, \$.01 par value; 60,000 and		
30,000 shares authorized, 14,627 and 15,037	146	150
shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively		
Additional paid-in-capital	61,735	81,685
Accumulated other comprehensive loss	(7,317)	(6,649)
Retained earnings	168,209	135,662
Total stockholders' equity	222,773	210,848
Total Liabilities and Stockholders' Equity	\$240,246	\$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 Three Months Ended December 31,					For the Year Ended December 31,						
	2016	%		2015	%		2016	%		2015	%	
Orthobiologics	\$24,376	86	%	\$21,530	84	%	\$89,695	87	%	\$73,247	84	%
Surgical	1,590	6	%	1,363	5	%	5,427	5	%	5,812	7	%
Dermal	1,114	4	%	1,134	5	%	2,759	3	%	2,266	2	%
Other	1,216	4	%	1,580	6	%	5,051	5	%	6,371	7	%

Product Revenue	\$28,296	100%	\$25,607	100%	\$102,932	100%	\$87,69	6 100%
Product Gross Profit	\$20,757		\$19,317		\$78,905		\$66,64	3
Product Gross Margin	73 %	6	75	%	77	%	76	%

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

	For the Th Ended De				For the Year Ended December 31,				
	2016	%	2015	%	2016	%	2015	%	
Geographic Region:									
United States	\$22,940	81 %	\$20,574	80 %	\$83,972	82 %	\$71,621	82 %	
Europe	2,696	10 %	2,462	10 %	10,953	10 %	8,756	10 %	
Other	2,660	9 %	2,571	10 %	8,007	8 %	7,319	8 %	
Product Revenue	\$28,296	100%	\$25,607	100%	\$102,932	100%	\$87,696	100%	

View source version on <u>businesswire.com</u>: <u>http://www.businesswire.com/news/home/20170215006178/en/</u>

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

Source: Anika Therapeutics, Inc.
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