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Anika Therapeutics Delivers Strong Performance with Record Product Revenue for the Fourth Quarter and Full Year 2015

Product Revenue Increased 43% Year-over-Year for Fourth Quarter of 2015

BEDFORD, Mass.--(BUSINESS WIRE)-- [Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global, integrated orthopedic medicines company specializing in therapeutics based on its proprietary [hyaluronic acid \("HA"\) technology](#), today reported financial results for the fourth quarter and full year ended December 31, 2015, along with business progress in the periods.

"We ended 2015 and entered 2016 with strong momentum in all aspects of our business -- commercial, clinical, operational, and financial," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "First, product revenue increased 43% year-over-year for the fourth quarter, and our viscosupplementation franchise delivered robust performance and remained on track for market leadership in 2017. Second, we continued to advance our late-stage HA-based pipeline candidates, CINGAL and HYALOFAST, through the clinical development and regulatory channels. Third, as part of our strategic shift towards direct commercialization, we are consolidating our global manufacturing operations at our U.S. headquarters. Finally, we renewed our interest in strategic M&A opportunities that could augment our thriving organic business, and create value for shareholders over the short and long terms."

Fourth Quarter and Full Year Financial Results

- | Product revenue grew 43% year-over-year for the fourth quarter of 2015, and 16% for the full year of 2015. The Company saw normal inventory purchase growth patterns resume in the fourth quarter after the conclusion of an inventory rebalancing by its U.S. commercial partner.
- | Total revenue for the fourth quarter of 2015 increased 33% to \$30.9 million, compared to \$23.3 million for the fourth quarter of 2014. The increase was primarily driven by the continued growth in Anika's viscosupplementation franchise worldwide. Total revenue for the full year of 2015 was \$93.0 million, compared to \$105.6 million for the full year of 2014. The decline was due to the receipt of \$30 million of licensing, milestone and contract revenue related to MONOVISC product approval, launch, and achievement of a unique CMS reimbursement code in 2014, which was partially offset by \$5 million of milestone revenue received in 2015 for the achievement of a target MONOVISC U.S. end user sales threshold.
- | ORTHOVISC maintained its position as the leading multiple-injection product. MONOVISC continued to hold the number two position in the single-injection segment. Overall, there was a 24% increase in the combined U.S. viscosupplementation end-user revenue in 2015, with MONOVISC end-user sales more than tripling year-over-year domestically.
- | The Company received a \$5.0 million milestone payment in the fourth quarter of 2015 from its U.S. commercial partner as a result of MONOVISC achieving \$50 million in end-user revenue in 2015.
- | Net income for the fourth quarter of 2015 increased 41% to \$11.0 million, or \$0.72 per diluted share, compared to \$7.8 million, or \$0.51 per diluted share, for the fourth quarter of 2014. Net income for the full year of 2015 was \$30.8 million, or \$2.01 per diluted share, compared to \$38.3 million, or \$2.51 per diluted share. Full-year 2014 results reflected the favorable impact of the \$30 million of licensing, milestone and contract revenue previously discussed.

Recent Business Highlights

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

- | The commencement of patient enrollment in the Company's HYALOFAST FastTRACK study. HYALOFAST, a biodegradable scaffold, is used to enable cartilage regeneration in patients suffering from cartilage defects. The FastTRACK study is a prospective, randomized, active treatment-controlled, multicenter study to establish the superiority of a hyaluronan-based scaffold (HYALOFAST) with autologous bone marrow aspirate concentrate (BMAC) in the treatment of articular knee cartilage defect lesions. It will enroll approximately 200 patients at up to 30 sites in the U.S. and Europe. HYALOFAST is CE Marked in Europe and is available commercially in 18 countries with more than 6,000 uses to date. European clinical data demonstrates that patients treated with HYALOFAST plus autologous

BMAC in a one-step, minimally invasive arthroscopic procedure were able to successfully regenerate hyaline-like cartilage. We believe HYALOFAST is poised to take a market leadership position.

- | The decision to pursue CINGAL approval in the U.S. through the New Drug Application pathway, and the approval of CINGAL by Health Canada for the treatment of pain associated with osteoarthritis of the knee.
- | An agreement with a new commercial partner in China for the commercialization of both MONOVISC and CINGAL.
- | Ongoing progress with full integration of the Company's global manufacturing operations under one roof in Anika's Bedford, Mass. global headquarters. This integration is intended to accelerate product development and to enable full control of the Company's supply chain.

Full Year 2016 Corporate Outlook

Looking forward to 2016, the Company expects total revenue growth to be in the mid-teen percentage range. The Company also anticipates continued headway on several key initiatives including:

- | Resolution of open items for the submission of CINGAL New Drug Application.
- | Approval of CINGAL in the E.U. and launch of CINGAL in Canada and Europe.
- | Advancement toward full patient enrollment in the Company's HYALOFAST FastTRACK study.
- | Integration of global manufacturing operations in Anika's Bedford, Mass. global headquarters.
- | Initial occupation of the Company's new Padua, Italy office, which will serve as its new European hub.
- | Progress in the development of a direct commercialization capability in the U.S.

Conference Call Information

Anika management will hold a conference call and webcast to discuss its financial results, business highlights and financial outlook tomorrow, Thursday, February 25th 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, Mass. Anika is committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing clinically meaningful therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. The Company has over two decades of expertise developing, manufacturing and commercializing more than 20 products, in markets across the globe, based on its proprietary [hyaluronic acid \(HA\) technology](#). Anika's orthopedic medicine portfolio is comprised of marketed ([ORTHOVISC®](#) and [MONOVISC®](#)) and pipeline (CINGAL® and HYALOFAST® in the U.S.) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration. For more information about Anika, please visit <http://www.anikatherapeutics.com>.

Forward-Looking Statements

The statements made in the second paragraph, the first and fourth bullet points in the section captioned "Recent Business Highlights," and the section captioned "Full Year 2016 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 direct commercialization capabilities, the Company's interest in strategic M&A transactions, enrollment rates in the HYALOFAST clinical study, the commercial potential of HYALOFAST, the integration of the Company's manufacturing operations, the approval of CINGAL in the European Union, and the Company's expected revenue growth. 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, including for HYALOFAST, 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, including for CINGAL; (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 operate 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Product revenue	\$ 25,607	\$ 17,880	\$ 87,696	\$ 75,474
Licensing, milestone and contract revenue	5,287	5,375	5,303	30,121
Total revenue	<u>30,894</u>	<u>23,255</u>	<u>92,999</u>	<u>105,595</u>
Operating expenses:				
Cost of product revenue	6,290	5,511	21,053	20,930
Research & development	3,016	1,984	8,987	8,144
Selling, general & administrative	4,524	3,673	14,825	15,074
Total operating expenses	<u>13,830</u>	<u>11,168</u>	<u>44,865</u>	<u>44,148</u>
Income from operations	17,064	12,087	48,134	61,447
Interest income, net	39	42	120	58
Income before income taxes	17,103	12,129	48,254	61,505
Provision for income taxes	6,061	4,313	17,496	23,186
Net income	<u>\$ 11,042</u>	<u>\$ 7,816</u>	<u>\$ 30,758</u>	<u>\$ 38,319</u>
Basic net income per share:				
Net income	\$ 0.74	\$ 0.53	\$ 2.06	\$ 2.61
Basic weighted average common shares outstanding	14,965	14,801	14,934	14,678
Diluted net income per share:				
Net income	\$ 0.72	\$ 0.51	\$ 2.01	\$ 2.51
Diluted weighted average common shares outstanding	15,353	15,278	15,321	15,269

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

ASSETS	December 31, 2015	December 31, 2014
Current assets:		
Cash and cash equivalents	\$ 110,707	\$ 100,156
Investments	27,751	6,750
Accounts receivable, net of reserves of \$167 and \$147 at December 31, 2015 and 2014, respectively	21,652	17,152

Inventories	14,938	12,407
Prepaid expenses and other current assets	1,385	1,371
Total current assets	176,433	137,836
Property and equipment, at cost	64,648	53,620
Less: accumulated depreciation	(24,540)	(21,951)
	40,108	31,669
Long-term deposits and other	69	69
Intangible assets, net	11,656	14,895
Goodwill	7,482	8,339
Total Assets	<u>\$ 235,748</u>	<u>\$ 192,808</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 8,302	\$ 1,201
Accrued expenses and other current liabilities	4,778	4,772
Income taxes payable	4,198	-
Total current liabilities	17,278	5,973
Other long-term liabilities	781	894
Long-term deferred revenue	66	102
Deferred tax liability	6,775	7,741
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at December 31, 2015 and December 31, 2014	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 15,036,808 and 14,851,703 shares issued and outstanding at December 31, 2015 and 2014, respectively	150	149
Additional paid-in-capital	81,685	77,540
Accumulated other comprehensive loss	(6,649)	(4,495)
Retained earnings	135,662	104,904
Total stockholders' equity	210,848	178,098
Total Liabilities and Stockholders' Equity	<u>\$ 235,748</u>	<u>\$ 192,808</u>

Anika Therapeutics, Inc. and Subsidiaries Supplemental Financial Data

Revenue by Product Line and Product Gross Margin

(in thousands, except percentages)

(unaudited)

	Quarter Ended December 31,		Year Ended December 31,		2015		2014	
	2015	%	2014	%	2015	%	2014	%
Orthobiologics	\$21,530	84%	\$13,207	74%	\$73,247	84%	\$61,957	82%
Surgical	1,363	5%	1,273	7%	5,812	7%	5,855	8%
Dermal	1,134	5%	395	2%	2,266	2%	1,334	2%
Other	1,580	6%	3,005	17%	6,371	7%	6,328	8%
Total Product Revenue	<u>\$25,607</u>	<u>100%</u>	<u>\$17,880</u>	<u>100%</u>	<u>\$87,696</u>	<u>100%</u>	<u>\$75,474</u>	<u>100%</u>
Product Gross Profit	\$19,317		\$12,369		\$66,643		\$54,544	
Product Gross Margin	75%		69%		76%		72%	

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

(unaudited)

	Quarter Ended December 31,				Year Ended December 31,			
	2015	%	2014	%	2015	%	2014	%
Geographic Location:								
United States	\$20,574	80%	\$14,324	80%	\$71,621	82%	\$62,606	83%
Europe	2,462	10%	936	5%	8,756	10%	6,204	8%
Other	2,571	10%	2,620	15%	7,319	8%	6,664	9%
Total Revenue	<u>\$25,607</u>	<u>100%</u>	<u>\$17,880</u>	<u>100%</u>	<u>\$87,696</u>	<u>100%</u>	<u>\$75,474</u>	<u>100%</u>

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