

Anika Reports Third Quarter 2017 Financial Results

Completed Enrollment in CINGAL Phase III Clinical Trial; Advancement of Regenerative Medicine Pipeline; MONOVISC Revenue Increased 50% Year-over-Year

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 third quarter ended September 30, 2017, along with business progress in the period.

"Anika made significant progress on multiple fronts executing its long-term growth strategy, highlighted by the early completion of enrollment in the CINGAL® Phase III trial, regulatory clearances for the expansion of MONOVISC® into India, Australia, and Taiwan, pipeline advancements and the bolstering of our executive and commercial leadership team," said Charles H. Sherwood, Ph.D., Chief Executive Officer. "MONOVISC continued to gain worldwide market share in the third quarter as physicians continue to migrate towards single-injection solutions, resulting in MONOVISC revenue growth of 50% year-over-year for the quarter. Additionally, we advanced our regenerative medicine pipeline with the submission of a 510(k) application to the U.S. Food and Drug Administration for our injectable HA-based bone repair treatment, a promising new opportunity gaining attention in the orthopedic space."

Third Quarter Financial Results

- Total revenue for the third quarter of 2017 increased 5% year-over-year to \$27.2 million, compared to \$25.8 million for the third quarter of 2016.
- Worldwide Orthobiologics revenue grew 7% year-over-year in the third quarter of 2017. The main driver of this product revenue growth was an increase in global MONOVISC revenue of 50% year-over-year in the third quarter of 2017, which was partially offset by the continued decline in ORTHOVISC® revenue in the same period, mirroring the industry shift from multiple- to single-injection therapies.
- International Orthobiologics revenue increased 10% year-over-year for the third quarter of 2017, due primarily to the global expansion of MONOVISC, as well as the growth of CINGAL. Domestically, ORTHOVISC and MONOVISC continue to maintain a combined market-leading position.
- Total operating expenses for the third quarter of 2017 were \$16.9 million, compared to \$12.1 million for the third quarter of 2016. The increase in total operating expenses was due primarily to higher research and development investments required to advance the Company's growing pipeline towards regulatory approvals, and the expansion of the commercial team in anticipation of those product launches.
- Net income for the third quarter of 2017 was \$6.9 million, or \$0.46 per diluted share, compared to \$9.0 million, or \$0.59 per diluted share, for the third quarter of 2016. The decline in net income was due primarily to the planned increase in operating expenses previously discussed.

Recent Business Highlights

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

- Completing enrollment well ahead of schedule in the second pivotal Phase III trial evaluating CINGAL, the Company's novel HA-corticosteroid combination viscosupplement for the treatment of symptoms associated with osteoarthritis (OA) of the knee. The Phase III trial, which will evaluate 576 patients with mild to moderate knee osteoarthritis, is designed to evaluate the safety of CINGAL as well as its effectiveness in improving pain, function, and quality of life measures over a 26-week period, in comparison to MONOVISC and triamcinolone hexacetonide. Enrollment was completed well ahead of internal estimates largely due to physician and patient interest, and enthusiasm surrounding the immediate and durable joint relief possible with CINGAL.
- Receiving regulatory approval for MONOVISC in India, Australia and Taiwan for the treatment of pain associated with osteoarthritis of all synovial joints. Sales in those countries are expected to begin in the fourth quarter of 2017.
- Advancing Anika's regenerative medicine pipeline with the submission of a 510(k) application to the U.S. Food

and Drug Administration for its injectable HA-based bone repair treatment. This treatment provides an injectable, self-setting, osteoconductive bone graft substitute that resorbs and is replaced by the growth of new bone during the healing process.

- Publishing data demonstrating the efficacy and safety of HYALOFAST® in combination with autologous adult mesenchymal stem cells for the treatment of cartilage lesions on the knee in the peer-reviewed journal *Knee Surgery Sports Traumatology Arthroscopy*.
- Strengthening the Company's executive leadership team with the appointments of Joseph Darling as President, Steven Chartier as Vice President of Regulatory and Clinical Affairs, and the anticipated appointment of Thomas Finnerty as Chief Human Resources Officer on October 30.
- Continued progress towards full consolidation of the Company's global manufacturing operations at Anika's Bedford, Massachusetts corporate headquarters.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights tomorrow, Thursday, October 26th 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 **HYALOFAST**, a solid HA-based scaffold to aid cartilage repair and regeneration. For more information about Anika, please visit www.anikatherapeutics.com.

Forward-Looking Statements

The statements made in the last sentence of the second bullet point and in the fifth bullet point in the section captioned "Recent Business Highlights" 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 sales expectations with regard to the Company's MONOVISC product and to the Company's appointment of personnel. 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)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Product revenue	\$27,178	\$25,783	\$78,899	\$74,636
Licensing, milestone and contract revenue	6	6	5,133	17
Total revenue	27,184	25,789	84,032	74,653
Operating expenses:				
Cost of product revenue	6,250	4,998	18,648	16,488
Research and development	5,842	2,822	14,521	7,773
Selling, general and administrative	4,823	4,280	14,862	12,525
Total operating expenses	16,915	12,100	48,031	36,786
Income from operations	10,269	13,689	36,001	37,867
Interest income, net	261	93	335	214
Income before income taxes	10,530	13,782	36,336	38,081
Provision for income taxes	3,643	4,830	12,587	13,619
Net income	\$6,887	\$8,952	\$23,749	\$24,462
Basic net income per share:				
Net income	\$0.47	\$0.61	\$1.63	\$1.66
Basic weighted average common shares outstanding	14,579	14,625	14,572	14,726
Diluted net income per share:				
Net income	\$0.46	\$0.59	\$1.58	\$1.61
Diluted weighted average common shares outstanding	15,115	15,077	15,065	15,163

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

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$126,960	\$104,261
Investments	25,750	20,500

Accounts receivable, net of reserves of \$217 and \$194 at September 31, 2017 and December 31, 2016, respectively	23,804	27,598
Inventories, net	20,252	15,983
Prepaid expenses and other current assets	2,268	2,098
Total current assets	199,034	170,440
Property and equipment, net	53,973	52,296
Other long-term assets	1,283	69
Intangible assets, net	10,738	10,227
Goodwill	8,104	7,214
Total assets	\$ 273,132	\$ 240,246

LIABILITIES AND
STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 5,189	\$ 2,303
Accrued expenses and other current liabilities	6,516	6,496
Total current liabilities	11,705	8,799
Other long-term liabilities	545	2,126
Deferred tax liability	7,593	6,548

Commitments and contingencies

Stockholders' equity:

Preferred stock, \$0.01 par value; 1,250 shares authorized, no shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Common stock, \$0.01 par value; 60,000 shares authorized, 14,662 and 14,627 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	146	146
Additional paid-in-capital	66,746	61,735
Accumulated other comprehensive loss	(5,047)	(7,317)
Retained earnings	191,444	168,209
Total stockholders' equity	253,289	222,773
Total liabilities and stockholders' equity	\$ 273,132	\$ 240,246

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

Product Line:	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2017	%	2016	%	2017	%	2016	%
Orthobiologics	\$23,990	88 %	\$22,428	87 %	\$68,686	87 %	\$65,319	88 %
Surgical	1,765	7 %	1,173	5 %	4,395	6 %	3,924	5 %
Dermal	358	1 %	594	2 %	1,235	2 %	1,558	2 %
Other	1,065	4 %	1,588	6 %	4,583	5 %	3,835	5 %
Product Revenue	\$27,178	100 %	\$25,783	100 %	\$78,899	100 %	\$74,636	100 %
Product Gross Profit	\$20,928		\$20,785		\$60,251		\$58,148	
Product Gross Margin	77%		81%		76%		78%	

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

Geographic Region:	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2017	%	2016	%	2017	%	2016	%
United States	\$22,227	82 %	\$21,126	82 %	\$63,507	81 %	\$61,032	82 %
Europe	2,832	10 %	2,703	10 %	9,743	12 %	8,240	11 %
Other	2,119	8 %	1,954	8 %	5,649	7 %	5,364	7 %
Product Revenue	\$27,178	100 %	\$25,783	100 %	\$78,899	100 %	\$74,636	100 %

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Source: Anika Therapeutics, Inc.

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