



Anika Reports Third Quarter 2018 Financial Results

CINGAL Drives Strong International Viscosupplement Revenue Growth Achieves Solid Bottom Line Performance with \$0.53 Diluted EPS

BEDFORD, Mass.--(BUSINESS WIRE)--Oct. 24, 2018--[Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global, integrated orthopedic and regenerative medicines company specializing in therapeutics based on its proprietary [hyaluronic acid \("HA"\) technology](#), today reported financial results for the third quarter ended September 30, 2018, and provided an update on its business progress in the period.

"Anika delivered solid financial results in the third quarter, while continuing to take important steps to accelerate revenue growth in 2019 and beyond," said Joseph Darling, President and Chief Executive Officer of Anika Therapeutics. "We are encouraged by the continued advances we are making across our deep pipeline and diverse commercial portfolio. During the quarter, CINGAL end user demand in Canada and Europe remained strong, and we were pleased to add four new distribution partners to further expand our commercial reach in Europe, Asia and South America. Focused international expansion efforts enabled us to realize a 31% year-over-year increase in international Viscosupplement revenue while we continued to generate strong earnings and cash flow. As we prepare to discuss the pathway for U.S. regulatory approval for CINGAL with the U.S. Food and Drug Administration in the first quarter of 2019, we believe Anika is well-positioned to transform into a global commercial company increasingly capable of generating significant value for our patients and shareholders."

Third Quarter Financial Results

- Total revenue for the third quarter of 2018 was \$26.8 million, compared to \$27.2 million for the third quarter of 2017. The year-over-year decline was due primarily to the impact from the voluntary recall of HYALOFAST, HYALOGRAFT-C, and HYALOMATRIX announced in May 2018.
- Global Viscosupplement revenue increased 2% year-over-year for the third quarter of 2018, while international Viscosupplement revenue increased 31% during the same period. The increases were primarily due to the growth of CINGAL in international markets, as well as the continued global expansion of Viscosupplement products overall.
- Total operating expenses for the third quarter of 2018 were \$18.2 million, compared to \$16.9 million for the third quarter of 2017. The increase in total operating expenses was due primarily to higher production costs and increased personnel and professional costs.
- Net income for the third quarter of 2018 increased to \$7.6 million, or \$0.53 per diluted share, compared to \$6.9 million, or \$0.46 per diluted share, for the third quarter of 2017. The increase in net income was due primarily to the reduction in R&D expenses as a result of the completion of the CINGAL 16-02 study and lower income tax expenses in 2018.

Recent Business Highlights

- Continued to work with external regulatory and legal experts to seek regulatory approval of CINGAL in the U.S. market. Anika plans to meet with the U.S. Food and Drug Administration (FDA) in the first quarter of 2019 and is developing multiple strategies to enable the company to move forward expeditiously once it has received guidance from the FDA regarding the pathway for CINGAL.
- Advanced the Company's product pipeline with the completion of preclinical development activities for its regenerative therapy for rotator cuff repair.
- Strengthened Anika's international product distribution network and expanded the Company's commercial reach with four new distribution partners in Europe, Asia and South America.
- Continued to evaluate potential partnership opportunities for the Company's expansive product pipeline as part of the ongoing work on its 5-year strategic plan.
- Convened an international distributor meeting at the Company's European headquarters to align key growth objectives and market approach strategies for 2019.

- Appointed Cheryl Blanchard, Ph.D., and Susan Vogt as new independent members of the Company's Board of Directors.

Full Year 2018 Revised Corporate Outlook

Based on currently available information, the Company anticipates full year product revenue to be approximately 3% below prior year. The Company continues to expect that it will resume the shipment of products that were the subject of the previously-disclosed voluntary recall by the end of this year. Total operating expenses are now expected to be reduced to the high \$80 million range for the full year of 2018 as a result of successful cost control initiatives.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights today, Wednesday, October 24 at 5:00 pm 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 and regenerative 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 tissue 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 paragraph of this press release and in the Section captioned "Full Year 2018 Corporate Outlook," 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 expected meeting with the U.S. Food and Drug Administration during the first quarter of 2019, the Company's full-year 2018 product revenue and operating expense projections, and the Company's expectations related to shipment of products previously subject to the voluntary recall. 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
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,	
	2018	2017	2018	2017
Product revenue	\$ 26,781	\$ 27,178	\$ 78,581	\$ 78,899
Licensing, milestone and contract revenue	6	6	18	5,133
Total revenue	26,787	27,184	78,599	84,032
Operating expenses:				
Cost of product revenue	8,282	6,250	24,279	18,648
Research and development	4,232	5,842	14,126	14,521
Selling, general and administrative	5,700	4,823	28,207	14,862
Total operating expenses	18,214	16,915	66,612	48,031
Income from operations	8,573	10,269	11,987	36,001
Interest and other income, net	522	261	907	335
Income before income taxes	9,095	10,530	12,894	36,336
Provision for income taxes	1,496	3,643	1,890	12,587
Net income	\$ 7,599	\$ 6,887	\$ 11,004	\$ 23,749
Basic net income per share:				
Net income	\$ 0.53	\$ 0.47	\$ 0.76	\$ 1.63
Basic weighted average common shares outstanding	14,237	14,579	14,524	14,572
Diluted net income per share:				
Net income	\$ 0.53	\$ 0.46	\$ 0.74	\$ 1.58
Diluted weighted average common shares outstanding	14,377	15,115	14,820	15,065

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

ASSETS	September 30, 2018	December 31, 2017
Current assets:		
Cash, cash equivalents and investments	\$ 149,011	\$ 157,256
Accounts receivable, net	20,771	23,825
Inventories, net	23,828	22,035
Prepaid expenses and other current assets	1,981	3,211
Total current assets	195,591	206,327
Property and equipment, net	55,041	56,183
Other long-term assets	1,109	1,254

Intangible assets, net	9,564	10,635
Goodwill	7,959	8,218
Total assets	\$ 269,264	\$ 282,617

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 2,462	\$ 6,747
Accrued expenses and other current liabilities	6,843	6,326
Total current liabilities	9,305	13,073
Other long-term liabilities	574	660
Deferred tax liability	4,120	5,393

Commitments and contingencies

Stockholders' equity:

Preferred stock, \$0.01 par value	-	-
Common stock, \$0.01 par value	142	147
Additional paid-in-capital	49,836	68,617
Accumulated other comprehensive loss	(5,228)	(4,784)
Retained earnings	210,515	199,511
Total stockholders' equity	255,265	263,491
Total liabilities and stockholders' equity	\$ 269,264	\$ 282,617

Anika Therapeutics, Inc. and Subsidiaries Supplemental Financial Data

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,			
	2018	%	2017	%	2018	%	2017	%
Orthobiologics	\$24,097	90 %	\$23,990	88 %	\$69,778	88 %	\$68,686	87 %
Surgical	1,191	4 %	1,765	7 %	3,700	5 %	4,395	6 %
Dermal	80	1 %	358	1 %	163	1 %	1,235	2 %
Other	1,413	5 %	1,065	4 %	4,940	6 %	4,583	5 %
Product Revenue	\$26,781	100 %	\$27,178	100 %	\$78,581	100 %	\$78,899	100 %
Product Gross Profit	\$18,499		\$20,928		\$54,302		\$60,251	
Product Gross Margin	69%		77%		69%		76%	

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

	For the Three Months Ended September 30,	For the Nine Months Ended September 30,
--	---	--

	2018	%	2017	%	2018	%	2017	%
Geographic Region:								
United States	\$21,695	81 %	\$22,227	82 %	\$63,377	81 %	\$63,507	81 %
Europe	3,132	12 %	2,832	10 %	9,021	11 %	9,743	12 %
Other	1,954	7 %	2,119	8 %	6,183	8 %	5,649	7 %
Product Revenue	\$26,781	100 %	\$27,178	100 %	\$78,581	100 %	\$78,899	100 %

View source version on businesswire.com: <https://www.businesswire.com/news/home/20181024005631/en/>

Source: Anika Therapeutics, Inc.

Anika Therapeutics, Inc.
Joseph Darling, 781-457-9000
President & CEO
or
Sylvia Cheung, 781-457-9000
CFO

<https://ir.anika.com/Anika-Reports-Third-Quarter-2018-Financial-Results>