

Anika Reports Fourth Quarter and Full Year 2018 Financial Results

Strong Bottom Line Performance with \$0.54 Diluted EPS for Fourth Quarter of 2018 MONOVISC and CINGAL Global Revenue Increased 14% for Full Year of 2018

BEDFORD, Mass.--(BUSINESS WIRE)--Feb. 21, 2019-- [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 fourth quarter and full year ended December 31, 2018, and provided an update on its business progress in the periods.

"Anika continued to deliver strong earnings and cash flow in the fourth quarter, entering 2019 well-positioned to further build on the foundation that will drive the Company's next phase of growth," said Joseph Darling, President and Chief Executive Officer of Anika Therapeutics. "During the quarter, MONOVISC and CINGAL end user demand remained strong. We also successfully expanded the reach of our orthobiologics business in Europe, Asia, Africa and South America with the addition of eight new international distributors during the year. We were pleased to resume global production and distribution of HYALOFAST, HYALOGRAFT-C and HYALOMATRIX, and look forward to benefitting from our full complement of products in 2019. We believe 2019 will be a transformational year for Anika and we will continue to take advantage of the multiple levers available to advance our long-term goal of returning to annual double-digit revenue growth. We are focused on solid execution and increasing efficiency and productivity, as we address our challenges and continue to expand our commercial reach, advance our pipeline and drive value for our shareholders."

Fourth Quarter and Full Year Financial Results

- Total revenue for the fourth quarter of 2018 was \$27.0 million, compared to \$29.4 million for the fourth quarter of 2017. Total revenue for the full year of 2018 was \$105.6 million, compared to \$113.4 million for the full year of 2017. The decrease in revenue for the quarter and full year of 2018 was due primarily to the impact from the voluntary recall and lower U.S. viscosupplement pricing. 2017 results also included the achievement of \$5.0 million of milestone revenue as a result of MONOVISC reaching \$100 million in U.S. end-user sales within a consecutive 12-month period.
- Global Viscosupplement revenue increased slightly for the full year of 2018. Global MONOVISC and CINGAL revenue increased 14% for the full year of 2018, providing evidence of strong favor toward the Company's innovative treatments.
- Total operating expenses for the fourth quarter of 2018 were \$17.2 million, compared to \$19.7 million for the fourth quarter of 2017. The year-over-year decrease in total operating expenses for the fourth quarter of 2018 was due primarily to lower cost of product revenue. Total operating expenses for the full year of 2018 were \$83.8 million, compared to \$67.7 million for the full year of 2017. The increase in total operating expenses for the full year of 2018 was due primarily to a one-time charge of \$8.4 million in the first quarter, which consisted mainly of non-cash stock-based compensation expense associated with the retirement of Anika's former Chief Executive Officer, approximately \$2.0 million of non-recurring CINGAL U.S. pre-launch market research activities in the first half of 2018, and increased personnel and professional service costs.
- Net income for the fourth quarter of 2018 was \$7.7 million, or \$0.54 per diluted share, compared to \$8.1 million, or \$0.53 per diluted share, for the fourth quarter of 2017. Net income for the full year of 2018 was \$18.7 million, or \$1.27 per diluted share, compared to \$31.8 million, or \$2.11 per diluted share, for the full year of 2017. The decline in net income for the full year of 2018 was due primarily to the decrease in total revenue and increase in operating expenses previously discussed.
- Cash, cash equivalents and investments were \$159.0 million as of December 31, 2018, compared to \$149.0 million as of September 30, 2018. Cash provided by operating activities was \$10.0 million for the fourth quarter of 2018 and approximately \$35.0 million for the full year of 2018.

Recent Business Highlights

- Resumed global distribution of HYALOFAST, HYALOGRAFT-C and HYALOMATRIX in the fourth quarter after a voluntary, non-safety related recall in the second quarter of 2018.
- Expanded the international commercial reach of the orthobiologics business in Europe, Asia, Africa and South America with the addition of eight new international distributors.
- Completed a product prototype of the Company's Rotator Cuff repair therapy as planned.
- On-track to complete a 5-year strategic plan in the first half of 2019.
- Continued evaluation of potential partnership opportunities for the Company's product pipeline, which is an important element of its 5-year strategic plan.

CINGAL FDA Update

Anika recently met with the U.S. Food and Drug Administration (FDA) to discuss the totality of available CINGAL data, including information from the 17-02 extension study and real world evidence from physicians in Canada and Europe, to gain additional guidance on the pathway for CINGAL approval in the U.S. Based on that meeting, it has become clear that Anika will need to conduct another Phase III clinical trial before it can obtain approval for CINGAL in the U.S. The Company plans to continue to work with the FDA and pursue the most expeditious path to FDA approval for CINGAL. The Company will provide updates on its progress on this initiative at appropriate intervals moving forward.

Full Year 2019 Corporate Outlook

For the full year of 2019, the Company expects total revenue to be approximately 3% to 6% below the prior year level due primarily to continued pricing pressures on its U.S. viscosupplement business. Licensing, milestone and contract revenue is expected to be flat for the year. Total operating expenses are anticipated to be in the high \$70 million to \$80 million range. Adjusted EBITDA is expected to be in the low \$30 million range, which is based on anticipated U.S. GAAP net income in the mid-teen to around \$20 million range. Capital expenditures are expected to be between \$5 million and \$8 million. In 2019, the Company plans to continue advancing key ongoing initiatives, including:

- Complete and begin implementation of Anika's 5-year strategic plan.
- Transform from a pure distributor model business by establishing a hybrid commercial model in the U.S., with the goal to launch the Company's first HA-based, surgically-delivered regenerative therapy for bone repair procedures in the second half of 2019.
- International expansion of Orthopedics and Dermal product portfolios.
- Develop and finalize a regulatory strategy for CINGAL in the U.S.
- Pursue strategic acquisitions and partnerships to augment organic growth.

Non-GAAP Outlook

The Company is stating its expectations regarding, and will report, its 2019 financial results with respect to Adjusted EBITDA, which is a non-GAAP financial measure and should not be considered an alternative to net income or other measurements under generally accepted accounting principles (GAAP). The Company believes that Adjusted EBITDA provides additional useful information to investors in their assessment of its operating performance as it is a metric used by management to evaluate the Company's performance. Adjusted EBITDA is not calculated identically by all companies, and therefore the Company's measurements of Adjusted EBITDA may not be comparable to similarly titled measures reported by other companies.

Adjusted EBITDA is defined by the Company as GAAP net income excluding depreciation and amortization, interest and other income (expense), income taxes, and share-based compensation expense. The Company is not providing a quantitative reconciliation of projected Adjusted EBITDA to the corresponding GAAP information because the GAAP measures that the Company excludes from its projected Adjusted EBITDA are not available without unreasonable effort on a forward-looking basis due to their unpredictability, high variability, complexity, and low visibility. These excluded GAAP measures include interest and other income, income taxes, and other charges. Because these charges may vary materially, they will have an unpredictable, and potentially significant, impact on our future GAAP results.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights today, Thursday, February 21 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 fifth and sixth sentences of the second paragraph, the fourth bullet point in the section captioned "Recent Business Highlights," the third sentence in the section captioned "CINGAL FDA Update," and those made in the section captioned "Full Year 2019 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 long-term strategies and growth plans, the status and completion of the Company's 5-year strategic plan, the Company's expectations with respect to its 2019 financial performance, the Company's U.S. and international commercial efforts, the Company's plans related to, and the development and finalization of a regulatory pathway for, CINGAL, and the Company's pursuit of strategic acquisitions and partnerships. 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) quarterly sales volume variation experienced by the Company, which can make future results difficult to predict and period-to-period comparisons potentially less meaningful; (x) the Company's ability to provide an adequate and timely supply of its products to its customers; and (xi) 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 December 31,		For the Twelve Months Ended December 31,	
	2018	2017	2018	2017
Product revenue	\$26,950	\$28,884	\$ 105,531	\$ 107,783
Licensing, milestone and contract revenue	6	504	24	5,637
Total revenue	26,956	29,388	105,555	113,420
Operating expenses:				
Cost of product revenue	7,001	8,716	31,280	27,364
Research & development	4,064	4,266	18,190	18,787
Selling, general & administrative	6,129	6,678	34,336	21,540
Total operating expenses	17,194	19,660	83,806	67,691
Income from operations	9,762	9,728	21,749	45,729
Interest and other income, net	551	138	1,458	473
Income before income taxes	10,313	9,866	23,207	46,202
Provision for income taxes	2,596	1,799	4,485	14,386
Net income	\$7,717	\$8,067	\$ 18,722	\$ 31,816
Basic net income per share:				
Net income	\$0.54	\$0.55	\$ 1.30	\$ 2.18
Basic weighted average common shares outstanding	14,168	14,596	14,442	14,575
Diluted net income per share:				
Net income	\$0.54	\$0.53	\$ 1.27	\$ 2.11
Diluted weighted average common shares outstanding	14,299	15,141	14,689	15,068

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash, cash equivalents and investments	\$ 159,014	\$ 157,256
Accounts receivable, net	20,775	23,825
Inventories, net	21,300	22,035
Prepaid expenses and other current assets	1,854	3,211
Total current assets	202,943	206,327
Property and equipment, net	54,111	56,183
Other long-term assets	4,897	1,254
Intangible assets, net	9,191	10,635
Goodwill	7,851	8,218

Total assets	\$278,993	\$282,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$3,143	\$6,747
Accrued expenses and other current liabilities	8,146	6,326
Total current liabilities	11,289	13,073
Other long-term liabilities	550	660
Deferred tax liability	3,542	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	50,763	68,617
Accumulated other comprehensive loss	(5,526)	(4,784)
Retained earnings	218,233	199,511
Total stockholders' equity	263,612	263,491
Total liabilities and stockholders' equity	\$278,993	\$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 December 31,				For the Twelve Months Ended December 31,			
	2018	%	2017	%	2018	%	2017	%
Orthobiologics	\$23,778	88 %	\$25,131	87 %	\$93,556	89 %	\$93,816	87 %
Surgical	1,814	7 %	867	3 %	5,514	5 %	5,262	5 %
Dermal	233	1 %	1,519	5 %	396	0 %	2,755	3 %
Other	1,125	4 %	1,367	5 %	6,065	6 %	5,950	5 %
Product Revenue	\$26,950	100 %	\$28,884	100 %	\$105,531	100 %	\$107,783	100 %
Product Gross Profit	\$19,949		\$20,168		\$74,251		\$80,419	
Product Gross Margin	74%		70%		70%		75%	

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

Geographic Region:	For the Three Months Ended December 31,				For the Twelve Months Ended December 31,			
	2018	%	2017	%	2018	%	2017	%
United States	\$21,974	82 %	\$23,783	82 %	\$85,351	81 %	\$87,290	81 %
Europe	2,709	10 %	2,692	9 %	11,730	11 %	12,435	12 %
Other	2,267	8 %	2,409	9 %	8,450	8 %	8,058	7 %
Product Revenue	\$26,950	100 %	\$28,884	100 %	\$105,531	100 %	\$107,783	100 %

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Source: Anika Therapeutics, Inc.

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<https://ir.anika.com/Anika-Reports-Fourth-Quarter-and-Full-Year-2018-Financial-Results>