Anika Investor Relations

Anika Reports Second Quarter 2019 Financial Results

Delivers Strong Bottom Line Performance with $0.67 Diluted EPS
CINGAL Revenue Drives International Viscosupplement Revenue Growth of 28% Year-over-Year
Announces Decision to Advance CINGAL Program Towards U.S. Regulatory Approval
Raises Full Year 2019 Revenue and Adjusted EBITDA Guidance

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 24, 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 second quarter ended June 30, 2019, and provided an update on its business progress in the period.

"Anika delivered strong earnings and cash flow in the second quarter, while we continued our transformation into a global commercial company," said Joseph Darling, President and Chief Executive Officer of Anika Therapeutics. "With an ongoing commitment to our people, products and performance, during the quarter we further strengthened our executive leadership team, continued to realize the benefits of our international expansion efforts and prepared for the launch of our first surgically-delivered therapy for bone repair procedures in the U.S. under our hybrid commercial model in the third quarter of 2019. Additionally, based on extensive analysis and discussions, and building on the strength of our international viscosupplement results, we have decided to move forward with our efforts to obtain regulatory approval for CINGAL in the U.S. Anika remains well positioned to deliver a continuum of orthopedic and regenerative medicine therapies and create sustained value for patients and shareholders."

Second Quarter Financial Results

- Total revenue for the second quarter of 2019 was $30.4 million, compared to $30.5 million for the second quarter of 2018.
- Global Viscosupplement revenue decreased slightly year-over-year for the second quarter of 2019. U.S. Viscosupplement revenue decreased 6% year-over-year for the quarter, due primarily to lower ORTHOVISC revenue. International Viscosupplement revenue increased 28% year-over-year for the quarter, primarily due to international CINGAL revenue growth of 125%.
- Total operating expenses for the second quarter of 2019 decreased to $18.5 million, compared to $19.3 million for the second quarter of 2018. The decrease in total operating expenses was due to lower cost of product revenue and research and development expenses, partially offset by higher selling, general and administrative expenses.
- Net income for the second quarter of 2019 was $9.4 million, or $0.67 per diluted share, compared to net income of $10.1 million, or $0.68 per diluted share, for the second quarter of 2018. The decrease in net income was due primarily to tax benefits from employee stock option exercises in the second quarter of 2018.
- Adjusted EBITDA (see description below) for the second quarter of 2019 increased to $14.8 million, compared to $14.0 million for the second quarter of 2018. The increase in adjusted EBITDA is primarily due to improvements in product gross profit and operating income as a result of more favorable revenue mix and a reduction in inventory related charges.
- Cash, cash equivalents and investments were $141.5 million as of June 30, 2019, compared to $159.0 million as of December 31, 2018. The decrease in cash, cash equivalents and investments was due to the Company's $30.0 million accelerated share repurchase program announced in May 2019, partially offset by strong operating cash flow for the first half of 2019. Cash provided by operating activities was $13.9 million for the first half of 2019.

Recent Business Highlights

- Completed the evaluation of CINGAL's clinical, regulatory, and commercial path forward, and determined to initiate a pilot study as the next step to advance CINGAL towards regulatory approval in the U.S. market. The pilot study is expected to enroll approximately 240 patients across 15 sites primarily located in the U.S. Patients will be randomized to receive either CINGAL, a steroid (triamcinolone hexacetonide), or saline placebo. The Company expects the pilot study to commence in the first half of 2020 and to take approximately one year to complete.
- Strengthened the executive leadership team with the appointment of James Loerop to the newly created position of Executive Vice President of Business Development and Strategic Planning. Mr. Loerop will oversee the Company's global business development function and advance its efforts to identify and evaluate potential acquisitions, partnerships, alliances, and licensing opportunities to expand the Company's commercial portfolio and global footprint.
- Continued to execute commercial expansion plans, including hiring three Regional Sales Directors to drive the upcoming launch of the Company's first surgically-delivered therapy for bone repair procedures in the U.S. utilizing a hybrid commercial model, which is planned for the third quarter of 2019.
- Executed a $30.0 million accelerated share repurchase (ASR) program in the second quarter of 2019, and received an initial delivery of approximately 450,000 shares of common stock. Anika expects the ASR program to be completed no later than the first quarter of 2020.
- Executing its five-year strategic plan, which Anika intends to present at its Analyst and Investor Day on September 18 in Boston.

Full Year 2019 Revised Corporate Outlook

Based on currently available information, the Company expects total revenue growth to be in the range of 1% to 4% for the full year of 2019. Total operating expenses are now anticipated to be in the high $70 million range, as a result of internal cost control initiatives. Adjusted EBITDA is now expected to be in the high $30 million to low $40 million range, which is based on anticipated U.S. GAAP net income around the mid $20 million range.

Non-GAAP Information

To supplement the financial measures prepared in accordance with U.S. generally accepted accounting principles (GAAP), the Company is reporting Adjusted EBITDA, which is a non-GAAP financial measure and should not be considered an alternative to net income or other measurements under 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 routinely 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 stock-based compensation expense. A reconciliation of Adjusted EBITDA to net income, the most directly comparable financial measure calculated and presented in accordance with GAAP, is shown in the table below for the three- and six-month periods ended June 30, 2019 and 2018 (in thousands).

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Net income	$ 9,435	$ 10,092	$ 13,942	$ 3,405
Interest and other income, net	(533)	(290)	(1,031)	(385)
Provision for income taxes	3,013	1,444	4,486	394
Depreciation and amortization	1,466	1,447	2,943	2,920
Stock-based compensation expense	1,443	1,322	2,829	8,887
Adjusted EBITDA	$ 14,824	$ 14,015	$ 23,169	$ 15,221

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights today, Wednesday, July 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®, viscosupplements 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 second and third sentences of the second paragraph, the first, third, and fourth bullet points in the section captioned "Recent Business Highlights," as well as the section captioned "Full Year 2019 Revised 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 plans for the launch of its surgically-delivered therapy for bone repair, the Company's plans to advance CINGAL for approval in the United States initially via a pilot study, the timing associated with the Company's ongoing ASR program, and the Company's revised expectations with respect to its 2019 financial performance. 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 June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Product revenue	$ 30,413	$ 30,542	$ 55,130	$ 51,800
Licensing, milestone and contract revenue	5	6	11	12
Total revenue	30,418	30,548	55,141	51,812

Operating expenses:				
Cost of product revenue	6,836	8,152	14,147	15,996
Research and development	4,165	4,733	8,423	9,895
Selling, general and administrative	7,502	6,417	15,174	22,507
Total operating expenses	18,503	19,302	37,744	48,398
Income from operations	11,915	11,246	17,397	3,414
Interest and other income, net	533	290	1,031	385
Income before income taxes	12,448	11,536	18,428	3,799
Provision for income taxes	3,013	1,444	4,486	394
Net income	$ 9,435	$ 10,092	$ 13,942	$ 3,405
Basic net income per share:				
Net income	$ 0.68	$ 0.69	$ 0.99	$ 0.23
Basic weighted average common shares outstanding	13,916	14,652	14,054	14,666
Diluted net income per share:				
Net income	$ 0.67	$ 0.68	$ 0.98	$ 0.23
Diluted weighted average common shares outstanding	14,088	14,915	14,203	15,045

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

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash, cash equivalents and investments	$ 141,452	$ 159,014
Accounts receivable, net	23,073	20,775
Inventories, net	22,986	21,300
Prepaid expenses and other current assets	2,413	1,854
Total current assets	189,924	202,943
Property and equipment, net	52,960	54,111
Operating lease right-of-use assets	23,495	-
Other long-term assets	4,884	4,897
Intangible assets, net	8,303	9,191

Goodwill	7,798	7,851
Total assets	$ 287,364	$ 278,993
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,287	$ 3,143
Accrued expenses and other current liabilities	8,101	8,146
Total current liabilities	10,388	11,289
Other long-term liabilities	373	550
Deferred tax liability	3,683	3,542
Operating lease liabilities	21,974	-
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value	-	-
Common stock, $0.01 par value	138	142
Additional paid-in-capital	24,329	50,763
Accumulated other comprehensive loss	(5,696)	(5,526)
Retained earnings	232,175	218,233
Total stockholders' equity	250,946	263,612
Total liabilities and stockholders' equity	$ 287,364	$ 278,993

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 June 30,				For the Six Months Ended June 30,			
Product Line:	2019	%	2018	%	2019	%	2018	%
Orthobiologics	$ 26,462	87 %	$ 26,192	86 %	$ 48,210	88 %	$ 45,681	88 %
Surgical	2,101	7 %	1,263	4 %	3,493	6 %	2,509	5 %
Dermal	444	1 %	623	2 %	573	1 %	83	0 %
Other	1,406	5 %	2,464	8 %	2,854	5 %	3,527	7 %
Product Revenue	$ 30,413	100 %	$ 30,542	100 %	$ 55,130	100 %	$ 51,800	100 %
Product Gross Profit	$ 23,577		$ 22,390		$ 40,983		$ 35,804	
Product Gross	78%		73%		74%		69%	

Margin

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

	For the Three Months Ended June 30,						For the Six Months Ended June 30,					
Geographic Region:	2019	%		2018	%		2019	%		2018	%	
United States	$22,937	76	%	$24,773	81	%	$43,026	78	%	$41,682	81	%
Europe	4,927	16	%	3,498	11	%	7,454	14	%	5,889	11	%
Other	2,549	8	%	2,271	8	%	4,650	8	%	4,229	8	%
Product Revenue	$30,413	100	%	$30,542	100	%	$55,130	100	%	$51,800	100	%

View source version on businesswire.com: https://www.businesswire.com/news/home/20190724005750/en/

Source: Anika Therapeutics, Inc.

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https://ir.anika.com/Anika-Reports-Second-Quarter-2019-Financial-Results