



Anika Reports Third Quarter Fiscal 2022 Financial Results

Third Quarter Revenue Growth of 2%

Third Phase III Clinical Trial for Cingal®, Next Generation Osteoarthritis Pain Product, Achieved Primary Endpoint Demonstrating Superiority Over Steroid Alone

Pivotal Phase III Clinical Trial for Hyalofast®, HA-Based, Single-Stage Cartilage Repair Product, Reaches 96% Enrollment

Positive Feedback from Limited Market Release of New X-Twist™ Fixation System for Soft Tissue Repair; On Track for Full Market Release in Early 2023

On Track to Achieve Stated FY2022 Guidance

BEDFORD, Mass., November 8, 2022 – [Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global joint preservation company in early intervention orthopedics, today reported financial results for its third quarter ended September 30, 2022.

Third Quarter 2022 Financial Summary

- Revenue in the third quarter of 2022 was \$40.3 million, up 2% compared with \$39.5 million in the third quarter of 2021.
 - OA Pain Management¹ revenue of \$25.7 million, down 2%
 - Joint Preservation and Restoration revenue of \$11.8 million, up 6%
 - Non-Orthopedic¹ revenue of \$2.8 million, up 27%
- Gross margin was 57%, including \$1.6 million of non-cash acquisition-related expenses and \$2.6 million product rationalization charges; Adjusted gross margin² was 67%.
- Net loss was (\$4.2) million, or (\$0.29) per share, compared to net income of \$0.6 million, or \$0.04 per diluted share, in the prior year. Adjusted net loss² was (\$0.7) million, or (\$0.05) per share, compared to adjusted net income² of \$0.8 million, or \$0.05 per diluted share, in the prior year.
- Adjusted EBITDA² was \$4.1 million, compared to adjusted EBITDA² of \$5.7 million in the prior year.
- Operating cash flow was \$2.7 million; quarter ending cash was \$87.8 million after a \$4.3 million payment for acquisition-related contingent consideration, with no outstanding debt.

¹ OA Pain Management was previously referred to as Joint Pain Management; Non-Orthopedic was previously referred to as Other.

² See description of non-GAAP financial information contained in this release.

"We're pleased with our third quarter accomplishments including our limited launch of the X-Twist Fixation System, successful results from our Cingal Phase III clinical trial, significant progress enrolling the Hyalofast pivotal clinical trial, and solid financial performance," Cheryl R. Blanchard, Ph.D., Anika's President and CEO, commented. "Our limited launch of the X-Twist platform has been very positive to date, and we remain on track for the full launch in early 2023. We also recently announced the successful results from our third Phase III clinical trial for Cingal which demonstrated superiority over steroid alone and we look forward to meeting with the FDA to determine next steps for U.S. regulatory approval. Despite the global macroeconomic environment, including staffing and supply chain challenges, we are confident that our strong cash position and no debt, robust foundation of clinical data, comprehensive product and technology portfolio, and exciting new product pipeline all position us for accelerated growth as we drive value for Anika shareholders."

Recent 2022 Business Highlights

- Continued Leadership in OA Pain Market**
 - Maintained #1 U.S. market share position in OA Pain Management with Monovisc® and Orthovisc®. In August 2022, DePuy Mitek extended our license and supply agreement for Orthovisc for another 5-year term through December 2028.
 - International viscosupplement sales continued accelerated growth, including Cingal which is currently sold in over 35 countries.
- Building a Best-in-Class Portfolio of Joint Preservation and Restoration Solutions**
 - Continued accelerated growth of Tactoset®, Anika's regenerative solution for insufficiency fractures and soft tissue hardware augmentation, with multiple planned 510(k) filings targeting further expansion.
 - First surgeries were performed with strong positive surgeon feedback during the limited market release of the X-Twist Fixation System, a new addition to the Anika sports medicine portfolio that addresses the needs of surgeons performing high volume soft tissue repair procedures, such as rotator cuff; on track for a full market release in early 2023.
 - Advanced development of multiple new products across the largest and fastest growing parts of the joint preservation market, including new innovative shoulder implants and a regenerative rotator cuff repair system.
- Ramping Up Medical Education Activities**
 - Held multiple medical education events, training more than 400 U.S. surgeons in-person to date this year in addition to other training activities at industry meetings.
- Advancing Cingal Towards U.S. Regulatory Approval**
 - Announced that Cingal, Anika's next generation product for osteoarthritis patients, successfully achieved its primary endpoint in a third Phase III clinical trial, Cingal 19-01, which demonstrated the superiority of Cingal over steroid alone, for OA pain relief at 26 weeks.
 - Together with previous studies, Cingal has now demonstrated superiority over each of its active ingredients and placebo, and consistently demonstrating strong and durable pain relief in OA patients.
 - Company to engage with the FDA in the coming months regarding next steps for U.S. regulatory approval and explore the potential to advance Cingal through commercial partnerships in the U.S. and select Asian markets. These efforts will inform next steps, including if and how to proceed with another clinical trial in the United States.
- Continuing Clinical Trial Enrollment for Hyalofast Pivotal Phase III Clinical Trial**
 - Delivered significant progress towards clinical study enrollment for the Company's differentiated HA-based single-stage cartilage repair product, Hyalofast, which is now 96% enrolled with 193 patients randomized between Hyalofast implantation and the microfracture surgical technique.
 - Company expects the trial to be fully enrolled in early 2023 and remains on track to file a Pre-Market Approval with the FDA in 2025.

Fiscal 2022 Outlook

The Company continues to expect its overall revenue for fiscal year 2022 to be toward the upper end of its guidance range of low to mid single-digit growth compared with 2021. Revenue ranges by product family are:

- OA Pain Management up mid to upper single-digit percent (previously low single-digit percent)

- Joint Preservation and Restoration up low to mid single-digit percent (previously mid single to low double-digit percent)
- Non-Orthopedic down approximately 20% due largely to legacy product rationalization

There remains volatility and uncertainty in the global macroeconomic environment and the Company's outlook for fiscal 2022 is subject to the changing dynamics associated with staffing shortages, supply chain disruption, inflation and other direct and indirect impacts of the COVID pandemic.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights today, Tuesday, November 8, 2022, at 5:00 pm ET. The conference call can be accessed by dialing 1-888-256-1007 (toll-free domestic) or 1-856-344-9221 (international) and providing the conference ID number 2205523. A live audio webcast will be available in the [Investor Relations](#) section of Anika's website, www.anika.com. A slide presentation with highlights from the conference call will be available in the Investor Relations section of 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

[Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. Leveraging our core expertise in hyaluronic acid and implant solutions, we partner with clinicians to provide minimally invasive products that restore active living for people around the world. Our focus is on high opportunity spaces within orthopedics, including osteoarthritis pain management, regenerative solutions, sports medicine soft tissue repair and bone preserving joint technologies, and our products are efficiently delivered in key sites of care, including ambulatory surgery centers. Anika's global operations are headquartered outside of Boston, Massachusetts. For more information about Anika, please visit www.anika.com.

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Non-GAAP Financial Information

Non-GAAP financial measures should be considered supplemental to, and not a substitute for, the Company's reported financial results prepared in accordance with GAAP. Furthermore, the Company's definition of non-GAAP measures may differ from similarly titled measures used by others. Because non-GAAP financial measures exclude the effect of items that will increase or decrease the Company's reported results of operations, Anika strongly encourages investors to review the Company's consolidated financial statements and publicly filed reports in their entirety. The Company presents these non-GAAP financial measures because it uses them as supplemental measures in internally assessing the Company's operating performance, and, in the case of Adjusted EBITDA, it is set as a key performance metric to determine executive compensation. The Company also recognizes that these non-GAAP measures are commonly used in determining business performance more broadly and believes that they are helpful to investors, securities analysts, and other interested parties as a measure of comparative operating performance from period to period.

Adjusted Gross Margin

Adjusted gross margin is defined by the Company as adjusted gross profit divided by total revenue. The Company defines adjusted gross profit as GAAP gross profit excluding amortization of certain acquired assets, the impact of inventory fair-value step up associated with our recent acquisitions and non-cash product rationalization charges.

Adjusted EBITDA

Adjusted EBITDA is defined by the Company as GAAP net income (loss) excluding depreciation and amortization, interest and other income (expense), income taxes, stock-based compensation expense, acquisition related expenses, non-cash charges related to goodwill impairment and changes in the fair value of contingent consideration associated with the Company's recent acquisitions as a result of the COVID pandemic, and non-cash product rationalization charges.

Adjusted Net Income (Loss) and Adjusted EPS

Adjusted net income (loss) is defined by the Company as GAAP net income excluding acquisition related expenses, inclusive of the impact of purchase accounting, on a tax effected basis, and the non-cash product rationalization charges. In the context of adjusted net income (loss), the impact of purchase accounting includes amortization of inventory step up and intangible assets recorded as part of purchase accounting for acquisition transactions. The amortized assets contribute to revenue generation, and the amortization of such assets will recur in future periods until such assets are fully amortized. These assets include the estimated fair value of certain identified assets acquired in acquisitions in 2020 and beyond, including in-process research and development, developed technology, customer relationships and acquired tradenames. As a result of COVID, the Company is also specifically excluding the impacts of goodwill impairment charges and changes in the fair value of contingent consideration associated with the acquisition transactions, each on a tax effected basis. Adjusted diluted EPS is defined by the Company as GAAP diluted EPS excluding acquisition related expenses and the impact of purchase accounting, each on a tax-adjusted per share basis, and non-cash product rationalization charges. Again, the Company is also specifically excluding the impacts of goodwill impairment charges and changes in the fair value of contingent consideration associated with recent acquisition transactions, each on a tax effected basis if applicable.

A reconciliation of adjusted gross profit to gross profit (and the associated adjusted gross margin calculation), adjusted EBITDA to net income (loss), adjusted net income (loss) to net income (loss) and adjusted diluted EPS to diluted EPS, the most directly comparable financial measures calculated and presented in accordance with GAAP, is shown in the tables at the end of this release.

Forward-Looking Statements

This press release may contain 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, concerning the Company's expectations, anticipations, intentions, beliefs or strategies regarding the future which are not statements of historical fact, including the subheadings at the top of the press release with respect to the planned launch of the X-Twist and FY2022 guidance, the second, third and final sentences of Dr. Blanchard's quote, the bullets with respect to the planned launch of the X-Twist, the anticipated meeting with the FDA and potential partnerships regarding Cingal, and the anticipated Hyalofast enrollment and filing of a Pre-Market Approval, all in the section titled Recent 2022 Business Highlights, and the statements made in the section titled Fiscal 2022 Outlook. 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.

For Investor Inquiries:

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	(unaudited)			
	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	\$ 40,264	\$ 39,536	\$ 116,614	\$ 111,973
Cost of Revenue	17,485	16,513	47,169	47,164
Gross Profit	22,779	23,023	69,445	64,809
Operating expenses:				
Research and development	7,301	7,673	20,433	21,327
Selling, general and administrative	21,276	17,500	61,745	53,664
Change in fair value of contingent consideration	-	(3,450)	-	(21,920)
Total operating expenses	28,577	21,723	82,178	53,071
(Loss) income from operations	(5,798)	1,300	(12,733)	11,738
Interest and other income (expense), net	436	(48)	378	(141)
(Loss) income before income taxes	(5,362)	1,252	(12,355)	11,597
(Benefit from) provision for income taxes	(1,187)	694	(2,404)	1,670
Net (loss) income	\$ (4,175)	\$ 558	\$ (9,951)	\$ 9,927
Net (loss) income per share:				
Basic	\$ (0.29)	\$ 0.04	\$ (0.68)	\$ 0.69
Diluted	\$ (0.29)	\$ 0.04	\$ (0.68)	\$ 0.68
Weighted average common shares outstanding:				
Basic	14,603	14,429	14,542	14,389
Diluted	14,603			

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash, cash equivalents and investments	\$ 87,777	\$ 94,386
Accounts receivable, net	34,168	29,843
Inventories, net	37,237	36,010
Prepaid expenses and other current assets	8,579	8,289
Total current assets	167,761	168,528
Property and equipment, net	47,390	47,602
Right-of-use assets	30,987	20,957
Other long-term assets	18,342	20,285
Intangible assets, net	76,545	82,382
Goodwill	6,721	7,781
Total assets	\$ 347,746	\$ 347,535
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,353	\$ 7,633
Accrued expenses and other current liabilities	17,999	17,847
Contingent consideration	-	4,315
Total current liabilities	26,352	29,795
Other long-term liabilities	474	1,258
Deferred tax liability	6,800	10,157
Lease liabilities	29,183	19,240
Stockholders' equity:		
Common stock, \$0.01 par value	146	144
Additional paid-in-capital	76,661	67,081
Accumulated other comprehensive loss	(7,497)	(5,718)
Retained earnings	215,627	225,578
Total stockholders' equity	284,937	287,085
Total liabilities and stockholders' equity	\$ 347,746	\$ 347,535

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of GAAP Gross Profit to Adjusted Gross Profit
(in thousands)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021

Gross Profit	\$ 22,779		\$ 23,023		\$ 69,445		\$ 64,809	
Product rationalization related charges	2,636				2,636		2,063	
Acquisition related intangible asset amortization	1,562		1,562		4,686		4,686	
Acquisition related inventory step up	-		1,458		-		6,244	
Adjusted Gross Profit	\$ 26,977		\$ 26,043		\$ 76,767		\$ 77,802	
Unadjusted Gross Margin	57	%	58	%	60	%	58	%
Adjusted Gross Margin	67	%	66	%	66	%	69	%

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of GAAP Net Income to Adjusted EBITDA
(in thousands)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Net (loss) income	\$ (4,175)	\$ 558	\$ (9,951)	\$ 9,927
Interest and other expense, net	(436)	48	(378)	141
Benefit from income taxes	(1,187)	694	(2,404)	1,670
Depreciation and amortization	1,549	1,789	4,980	5,226
Stock-based compensation	3,876	2,863	10,502	7,919
Product rationalization	2,636	-	2,636	2,063
Acquisition related intangible asset amortization	1,787	1,787	5,361	5,361
Acquisition related inventory step up	-	1,458	-	6,244
Change in fair value of contingent consideration	-	(3,450)	-	(21,920)
Adjusted EBITDA	\$ 4,050	\$ 5,747	\$ 10,746	\$ 16,631

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of GAAP Net Income to Adjusted Net Income
(in thousands)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Net (loss) income	\$ (4,175)	\$ 558	\$ (9,951)	\$ 9,927
Product rationalization, tax effected	2,056	-	1,947	1,590
Acquisition related intangible asset amortization, tax effected	1,394	1,146	3,960	3,898
Acquisition related inventory step up, tax effected	-	935	-	4,626
Change in fair value of contingent consideration, tax effected	-	(1,865)	-	(17,152)
Adjusted net (loss) income	\$ (725)	\$ 774	\$ (4,044)	\$ 2,889

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of GAAP Diluted Earnings Per Share to Adjusted Diluted Earnings Per Share
(per share data)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Diluted (loss) earnings per share (EPS)	\$ (0.29)	\$ 0.04	\$ (0.68)	\$ 0.68
Product rationalization, tax effected	0.14	-	0.13	0.11
Acquisition related intangible asset amortization, tax effected	0.10	0.08	0.27	0.27
Acquisition related inventory step up, tax effected	-	0.06	-	0.32
Change in fair value of contingent consideration, tax effected	-	(0.13)	-	(1.18)
Adjusted diluted (loss) earnings per share (EPS)	\$ (0.05)	\$ 0.05	\$ (0.28)	\$ 0.20

Anika Therapeutics, Inc. and Subsidiaries
Revenue by Product Family
(in thousands, except percentages)
(unaudited)

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2022	2021	\$ change	% change	2022	2021	\$ change	% change
OA Pain Management	\$ 25,665	\$ 26,153	\$ (488)	-2	\$ 74,139	\$ 69,790	\$ 4,349	6
Joint Preservation and Restoration	11,821	11,193	628	6	36,055	35,296	759	2

Non-Orthopedic	2,778	2,190	588	27	%	6,420	6,887	(467)	-7	%
Revenue	\$ 40,264	\$ 39,536	\$ 728	2	%	\$ 116,614	\$ 111,973	\$ 4,641	4	%

<https://ir.anika.com/2022-11-08-Anika-Reports-Third-Quarter-Fiscal-2022-Financial-Results>