

Anika Reports Second Quarter 2025 Financial Results

Regenerative Solutions revenue up 41% with Integrity™ Implant System ahead of expectations and continued strong Hyalofast® growth; Integrity surpasses full year 2024 performance and is on pace to more than double in 2025

Company released topline results for Hyalofast® clinical trial which did not meet pre-specified co-primary endpoints; Hyalofast demonstrated statistically significant improvements in pre-defined secondary endpoints and other measures; Company plans to file the final PMA module in second half 2025

Reaffirming Fiscal 2025 Revenue and EBITDA guidance; revising long-term outlook to reflect potential timing of FDA review for Hyalofast launch

BEDFORD, Mass., July 29, 2025 (GLOBE NEWSWIRE) -- Anika Therapeutics, Inc. (Nasdaq: ANIK), a global leader in the osteoarthritis ("OA") pain management and regenerative solutions spaces focused on early intervention orthopedics, today announced financial results for the second quarter ended June 30, 2025.

Second Quarter 2025 Results

Anika reported second quarter revenue from continuing operations of \$28.2 million, an 8% decrease compared to the same period in 2024. Commercial Channel revenue was flat year-over-year, while OEM Channel revenue, which includes U.S. OA Pain Management, was down 13% in line with expectations. The decline was driven by lower pricing for Monovisc® and Orthovisc®, sold by our commercial partner, J&J MedTech.

Cheryl Blanchard, President and CEO of Anika Therapeutics, commented: "We continue to see strength in our Commercial Channel with Regenerative Solutions revenue increasing 41% in the quarter driven by Integrity's outperformance and continued strong International Hyalofast growth. International OA Pain Management revenue was modestly lower in the quarter; however, remained flat through the first half of 2025, reflecting increased order demand in Q2 2024 and the temporary impact of our recent production yield issues. Importantly, there was no impact on delivery of products to patients as a result of these temporary issues and in June we returned to full production. After a challenging first quarter, pricing for US OA Pain Management products rebounded in the second quarter and is expected to represent the high point for the year. As previously communicated, we anticipate a more pronounced decline in pricing during the second half of 2025, with normalization expected as we enter 2026 as end-user pricing for Monovisc and Orthovisc converge more in line with market competitors. From an expense perspective, we continue to make excellent progress on our cost-saving measures, resulting in a 17% decline in operating expenses for the quarter."

Dr. Blanchard continued: "Earlier today we announced topline results of our U.S. Hyalofast clinical trial. While we are disappointed that the study did not meet its pre-specified co-primary endpoints, we are encouraged by the consistent improvements Hyalofast demonstrated over microfracture, including statistically significant improvements in pre-defined secondary endpoints and other measures. These results, combined with clinical data from over 15-years of successful real-world use in Europe, reinforce our confidence in Hyalofast's potential to address a critical unmet need in cartilage repair. We remain committed to advancing this breakthrough therapy and look forward to submitting the final PMA module to the FDA later this year, as planned."

Strong Integrity Commercial Performance and Portfolio Expansion

Integrity procedures grew for the fifth consecutive quarter and are on track to significantly outpace the overall growth of the U.S. soft tissue augmentation market. During the quarter, Anika received FDA 510(k) clearance to expand the Integrity platform with new shapes and sizes. The newly cleared 40x60mm and 25x60mm Integrity implants are expected to be available for a limited release in the U.S. by year-end, initially targeting Achilles repair in the foot and other larger tendon applications in the knee and hip. These additions are anticipated to drive increased adoption and support continued commercial momentum into 2026.

International OA Pain Management in Line with Previous Quarters

Anika's International Sales organization continues to deliver strong results, driven by increased market share and successful entry into new markets. Second quarter revenue grew 5% sequentially, though declined 10% year-over-year, primarily due to order timing in 2024 and the temporary impact of recent production-related yield issues. Anika expects the effects of the production yield issues to be fully resolved by the end of the third quarter and remains confident in its ability to achieve full-year 2025 International OA Pain Management growth projections.

Hyalofast Clinical Study Results and Program Update

Earlier today, Anika announced topline results from its U.S. Phase III FastTRACK clinical trial evaluating Hyalofast, a single-stage, resorbable, hyaluronic acid scaffold for cartilage repair. Although the study did not achieve its pre-specified co-primary endpoints for pain and function, Hyalofast demonstrated consistent improvements over microfracture, including statistically significant improvements in secondary endpoints and other measures such as KOOS Sports and Recreation Function, Quality of Life, and Total KOOS. The study was likely impacted by both a higher subject dropout rate in the microfracture arm and missed visits during COVID. Based on the strength and consistency of the overall data including clinical data from independent clinical studies performed outside the U.S. over the past 15 years, Anika intends to submit the final PMA module in the second half of 2025 as previously disclosed. Please refer to the press release issued this morning for additional details.

Progress on Final Steps to Cingal NDA Filing

During the quarter, Anika advanced key activities toward filing the NDA for Cingal, its novel, next-generation, non-opioid, single-injection OA Pain Management product, consisting of its proprietary cross-linked hyaluronic acid combined with a fast-acting steroid. These activities included progress on the ongoing toxicity studies and preparations for the bioequivalence study planned to start later this year. The completion of these two studies will mark a significant milestone and remain the final requirements for NDA submission in the U.S.

Operations Update

Anika has resolved the production yield issues it faced earlier this year. Throughout this period, the company maintained uninterrupted product supply to ensure no impact on patient treatments. The current focus is on replenishing distributor inventory levels through the third quarter. With improvements now in place, Anika expects increased throughput of Monovisc and Cingal, and is enhancing plant capacity to support future growth.

Update on Previously Announced Divestitures

Anika has now successfully completed all material transitional services with respect to the sale of both ArthroSurface and Parcus Medical.

Second Quarter 2025 Continuing Operations Financial Summary (compared to the second quarter of 2024)

- Revenue \$28.2 million, decreased 8%
 - OEM Channel revenue \$16.3 million, decreased 13%
 - Commercial Channel revenue \$11.9 million, flat
- Gross margin 51% (including \$3.0 million of inventory obsolescence and scrap charges in the quarter related to lower production yields)
- Operating expenses \$18.5 million, decreased 17%
- Loss from continuing operations (\$4.6) million, (\$0.33) per share
- Adjusted net loss from continuing operations¹ (\$1.7) million, (\$0.13) per share
- Adjusted EBITDA¹ (\$0.2) million
- Cash used in operating activities for total Company \$0.2 million
- Cash balance \$53.2 million

¹ See description of non-GAAP financial information contained in this release.

Maintaining Fiscal 2025 Guidance

Anika maintains 2025 revenue ranges by channel as follows:

- Commercial Channel, unchanged, of \$47 to \$49.5 million, up 12% to 18% year-over-year
- OEM Channel, unchanged, of \$62 to \$65 million, down 16% to 20% year-over-year

Anika maintains Adjusted EBITDA of -3% to 3%

Updating 2026-2027 Long Term Revenue Guidance for Potential Delay of Hyalofast Launch

Commercial Channel expected to grow +10% to +20% in 2026 and 2027 as compared to the previous guidance of +20% to +30% in 2026 and 2027, based on the anticipated launch of Hyalofast now in 2027. The company assumes \$3 million of initial sales in 2027 for Hyalofast.

Conference Call and Webcast Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights today, Wednesday, July 30, 2025, at 8:30 am ET. The conference call can be accessed by dialing 1-800-717-1738 (toll-free domestic) or 1-646-307-1865 (international) and providing the conference ID number 48251. 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 the global leader in the design, development, manufacturing, and commercialization of hyaluronic acid innovations. In partnership with clinicians, our sole focus is dedicated to delivering and advancing osteoarthritis pain management and orthopedic regenerative solutions. At our core is a passion to deliver a differentiated portfolio that improves patient outcomes around the world. 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 Information¹

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 EBITDA

Adjusted EBITDA is defined by the Company as GAAP net income (loss) from continuing operations excluding depreciation and amortization, interest and other income (expense), income taxes, stock-based compensation expense, and shareholder activism costs.

Adjusted Net Income (Loss) from Continuing Operations and Adjusted EPS from Continuing Operations

Adjusted net income (loss) is defined by the Company as GAAP net income from continuing operations, on a tax effected basis, excluding stock-based compensation. Adjusted diluted EPS from continuing operations is defined by the Company as GAAP diluted EPS from continuing operations excluding stock-based compensation.

A reconciliation of adjusted EBITDA to adjusted net income (loss) from continuing operations to net income (loss) from continuing operations and adjusted diluted EPS from continuing operations to diluted EPS from continuing operations, 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 statements about the planned launch of new shape and sizes and the potential growth of the Integrity Implant System, statements in Dr. Blanchard's quote about anticipated pricing of Monovisc and Orthovisc in the U.S., statements about the timing and potential success of the clinical and regulatory pathway and launch of Hyalofast in the U.S., statements about the anticipated regulatory pathway for the NDA filing for Cingal, statements about the final resolution of the impacts of the production yield issues experienced earlier in the year, and in the section titled "Maintaining Fiscal 2025 Guidance" and "Updating 2026-2027 Long Term Revenue Guidance for Potential Delay of Hyalofast Launch". 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, or to timely file domestic and international pre-market approval applications, 510(k) applications, or new drug applications, including the third PMA module for Hyalofast, (iii) that the FDA or other regulatory bodies may not approve or clear the Company's applications, including the Hyalofast PMA because of the failure to achieve the pre-defined primary endpoints or because the FDA may determine that achievement of secondary endpoints and/or post hoc data analyses are not sufficient to support approval; (iii) that such approvals or clearances 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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Anika Therapeutics, Inc. and Subsidiaries Consolidated Statements of Operations (in thousands, except per share data) (unaudited)

	For the Three Months Ended June 30,	
	2025	2024
Revenue	\$ 28,219	\$ 30,724
Cost of Revenue	13,856	10,235
Gross Profit	14,363	20,489
Operating expenses:		
Research and development	6,313	6,682
Selling, general and administrative	12,230	15,617
Total operating expenses	18,543	22,299
Loss from operations	(4,180)	(1,810)
Interest and other income (expense), net	214	595

Loss before income taxes	(3,966)	(1,215)	
Provision for income taxes	681	1,326	
Loss from continuing operations	(4,647)	(2,541)	
Loss from discontinued operations, net of tax	677	2,453	
Net loss	<u>\$ (3,970)</u>	<u>\$ (88)</u>	<u>\$</u>
Net loss per share:			
Basic			
Continuing Operations	\$ (0.33)	\$ (0.17)	\$
Discontinued Operations	\$ 0.05	\$ 0.16	\$
	<u>\$ (0.28)</u>	<u>\$ (0.01)</u>	<u>\$</u>
Diluted			
Continuing Operations	\$ (0.33)	\$ (0.17)	\$
Discontinued Operations	\$ 0.05	\$ 0.17	\$
	<u>\$ (0.28)</u>	<u>\$ (0.00)</u>	<u>\$</u>
Weighted average common shares outstanding:			
Basic	14,364	14,839	
Diluted	14,517	14,856	

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

ASSETS

Current assets:			
Cash and cash equivalents			\$
Accounts receivable, net			
Inventories, net			
Prepaid expenses and other current assets			
Current assets held for sale			
Total current assets			<u>—</u>
Property and equipment, net			
Right-of-use assets			
Other long-term assets			
Notes receivable			
Deferred tax assets			
Intangible assets, net			
Goodwill			
Non-current assets held for sale			
Total assets			<u>\$</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:			
Accounts payable			\$
Accrued expenses and other current liabilities			
Current liabilities held for sale			
Total current liabilities			<u>—</u>
Other long-term liabilities			
Lease liabilities			
Non-current liabilities held for sale			
Stockholders' equity:			
Common stock, \$0.01 par value			
Additional paid-in-capital			
Accumulated other comprehensive loss			
Retained earnings			
Total stockholders' equity			<u>—</u>
Total liabilities and stockholders' equity			<u>\$</u>

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of GAAP Net Loss from Continued Operations to Adjusted EBITDA
(in thousands)
(unaudited)

	For the Three Months Ended June 30,		
	2025	2024	
Net loss from continuing operations	\$ (4,647)	\$ (2,541)	\$
Interest and other (income) expense, net	(214)	(595)	
Provision for income taxes	681	1,326	
Depreciation and amortization	1,444	1,376	

Stock-based compensation	2,548	3,535	
Costs of shareholder activism	-	1,584	
Adjusted EBITDA	<u>\$ (188)</u>	<u>\$ 4,685</u>	<u>\$</u>

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

	For the Three Months Ended June 30,		
	2025	2024	
Loss from continuing operations	\$ (4,647)	\$ (2,541)	\$
Share-based compensation, tax effected	2,986	2,176	
Costs of shareholder activism, tax effected	-	975	
Adjusted net (loss) income from continuing operations	<u>\$ (1,661)</u>	<u>\$ 610</u>	<u>\$</u>

Anika Therapeutics, Inc. and Subsidiaries
Reconciliation of GAAP Diluted Earnings from Continuing Operations Per Share to Adjusted Diluted Earnings from Continuing Operations Per Share
(in thousands, except per share data)
(unaudited)

	For the Three Months Ended June 30,		
	2025	2024	
Diluted loss from continuing operations per share	\$ (0.33)	\$ (0.17)	\$
Share-based compensation, tax effected	0.20	0.14	
Costs of shareholder activism, tax effected	-	0.07	
Adjusted diluted net (loss) income per share	<u>\$ (0.13)</u>	<u>\$ 0.04</u>	<u>\$</u>

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

	For the Three Months Ended June 30,				
	2025	2024	\$ change	% change	2025
OEM Channel	\$ 16,340	\$ 18,887	\$ (2,547)	-13%	\$ 31,249
Commercial Channel	11,879	11,837	42	0%	23,138
Revenue	<u>\$ 28,219</u>	<u>\$ 30,724</u>	<u>\$ (2,505)</u>	<u>-8%</u>	<u>\$ 54,387</u>