

# ANIKA THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

Filed 02/21/18 for the Period Ending 02/21/18

Address	32 WIGGINS AVENUE BEDFORD, MA, 01730
Telephone	(781) 457-9000
CIK	0000898437
Symbol	ANIK
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 21, 2018

**Anika Therapeutics, Inc.**  
( Exact name of registrant as specified in its charter )

Massachusetts  
(State or other jurisdiction of  
incorporation or organization)

000-21326  
Commission file number

04-3145961  
(I.R.S. Employer  
Identification No.)

32 Wiggins Avenue, Bedford, MA 01730  
(Address of principal executive offices) (Zip code)

( 781)-457-9000  
Registrant's telephone number, including area code:

Not Applicable  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operations and Financial Condition.**

The following information, including the exhibit attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

On February 21, 2018, Anika Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and twelve months ended December 31, 2018. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

99.1 Press Release of Anika Therapeutics, Inc. dated February 21, 2018.

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99.1

[Press Release of Anika Therapeutics, Inc. dated February 21, 2018.](#)

**Anika Reports Fourth Quarter and Full Year 2017 Financial Results*****MONOVISC Global Revenue Increased 21% Year-over-Year for Fourth Quarter of 2017;  
Total Revenue Increased 10% for Full Year of 2017***

BEDFORD, Mass.--(BUSINESS WIRE)--February 21, 2018--Anika Therapeutics, Inc. (NASDAQ: ANIK), a global, integrated orthopedic 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, 2017, along with business progress in the periods.

“2017 was a year of significant achievement for Anika, highlighted by double-digit revenue growth, expansion of MONOVISC® and CINGAL® into new international markets, completion of the CINGAL Phase III trial enrollment ahead of schedule, and the strengthening of our executive team,” said Charles H. Sherwood, Ph.D., Chief Executive Officer. “As we look to 2018, we are poised to complete the CINGAL Phase III trial and submit a New Drug Application to the FDA. Our strategic objectives are focused on global commercial expansion, pipeline advancement, and the development of a direct commercialization capability in the U.S. to accelerate our revenue and earnings growth in the years ahead and to create sustained value for our shareholders.”

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## Fourth Quarter and Full Year Financial Results

- Total revenue for the fourth quarter of 2017 was \$29.4 million, compared to \$28.7 million for the fourth quarter of 2016. Total revenue for the full year of 2017 grew 10% to \$113.4 million, compared to \$103.4 million for the full year of 2016. Total revenue for the full year of 2017 included \$5.0 million in milestone revenue earned in the second quarter as a result of MONOVISC achieving \$100 million in U.S. end-user sales within a consecutive 12-month period ending in June 2017.
- Product revenue increased 2% year-over-year in the fourth quarter of 2017. MONOVISC revenue grew 21% year-over-year in the fourth quarter of 2017, which was partially offset by the decline in ORTHOVISC® revenue in the same period, following the industry shift from multiple to single injection therapies. For the full year of 2017, product revenue increased 5% and MONOVISC global revenue grew 29%, which was the primary overall revenue growth driver.
- International Orthobiologics revenue increased 22% for the full year of 2017, due primarily to the global expansion of MONOVISC, as well as the growth of CINGAL in international markets. Domestically, ORTHOVISC and MONOVISC continued to maintain a combined market-leading position.
- Total operating expenses for the fourth quarter of 2017 were \$19.7 million, compared to \$16.0 million for the fourth quarter of 2016. The increase in total operating expenses was due primarily to higher research and development investments required to advance the Company's growing pipeline towards regulatory approvals and to expand the commercial team in anticipation of those product launches. Total operating expenses for the full year of 2017 were \$67.7 million, compared to \$52.8 million for the full year of 2016.
- Net income for the fourth quarter of 2017 was \$8.1 million, or \$0.53 per diluted share, compared to \$8.1 million, or \$0.54 per diluted share, for the fourth quarter of 2016. Net income for the fourth quarter of 2017 included a one-time tax benefit of \$2.3 million, or \$0.15 per diluted share, resulting from the recently enacted U.S. tax reform legislation. Net income for the full year of 2017 was \$31.8 million, or \$2.11 per diluted share, compared to \$32.5 million, or \$2.15 per diluted share, for the full year of 2016.

## Recent Business Highlights

The Company made key commercial, operational, pipeline, and financial advancements, including:

- Expanding CINGAL and MONOVISC international presence, with MONOVISC product approvals and related commercial launches in India, Australia, and Taiwan.
  - Advancing its product pipeline with completion of patient enrollment in the CINGAL Phase III clinical study, and continued progress on enrolling patients in the FastTRACK Phase III HYALOFAST® Study for cartilage repair.
  - Expanding Anika's regenerative medicine portfolio with 510(k) clearance from the FDA for its injectable HA-based bone repair treatment.
  - Expanding its strategic collaboration with the Institute for Applied Life Sciences at the University of Massachusetts Amherst to continue the development of an innovative therapy for the treatment of rheumatoid arthritis, and with the Institute of Integrative Biology at the University of Liverpool to collaborate on research to develop an injectable mesenchymal stem cell therapy for the treatment of osteoarthritis.
  - Completed all planned activities related to the consolidation of the Company's global manufacturing operations at Anika's Bedford, Massachusetts corporate headquarters.
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**Full Year 2018 Corporate Outlook**

Looking forward to 2018, the Company expects total revenue growth to be around the mid-single digit percentage range for the full year of 2018. Licensing, milestone and contract revenue is expected to be \$5 million for the year. The Company also anticipates continued headway on several key initiatives including:

- Completion of the Phase III clinical trial of CINGAL, and the submission of a New Drug Application to the FDA for CINGAL;
- International expansion of MONOVISC and CINGAL;
- Continued progress toward the development of a direct commercialization capability in the U.S.; and
- Expanding Anika's regenerative medicine pipeline with a new product candidate for rotator cuff repair.

**Conference Call Information**

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights tomorrow, Thursday, February 22 at 9:00 am 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](http://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.

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**About Anika Therapeutics, Inc.**

Anika Therapeutics, Inc. (NASDAQ: ANIK) is a global, integrated orthopedic 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 cartilage 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](http://www.anikatherapeutics.com).

**Forward-Looking Statements**

*The statements made in the last sentence of the second paragraph and those made in the section titled "Full Year 2018 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 completion of the Company's CINGAL clinical trial and associated regulatory submission, the Company's development of, and goals associated with, its direct commercial capability, the Company's expectations regarding its 2018 financial performance, the international expansion of the Company's viscosupplementation product lines, and the expansion of the Company's regenerative medicine portfolio. 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](http://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.*

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**Anika Therapeutics, Inc. and Subsidiaries**  
**Consolidated Statements of Operations**  
**(in thousands, except per share data)**  
(unaudited)

	<b>For the Three Months Ended December 31,</b>		<b>For the Twelve Months Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Product revenue	\$ 28,884	\$ 28,296	\$ 107,783	\$ 102,932
Licensing, milestone and contract revenue	504	430	5,637	447
Total revenue	<u>29,388</u>	<u>28,726</u>	<u>113,420</u>	<u>103,379</u>
Operating expenses:				
Cost of product revenue	8,716	7,539	27,364	24,027
Research and development	4,266	2,959	18,787	10,732
Selling, general and administrative	6,678	5,488	21,540	18,013
Total operating expenses	<u>19,660</u>	<u>15,986</u>	<u>67,691</u>	<u>52,772</u>
Income from operations	9,728	12,740	45,729	50,607
Interest income, net	138	49	473	263
Income before income taxes	9,866	12,789	46,202	50,870
Provision for income taxes	1,799	4,704	14,386	18,323
Net income	<u>\$ 8,067</u>	<u>\$ 8,085</u>	<u>\$ 31,816</u>	<u>\$ 32,547</u>
Basic net income per share:				
Net income	\$ 0.55	\$ 0.56	\$ 2.18	\$ 2.22
Basic weighted average common shares outstanding	14,596	14,538	14,575	14,682
Diluted net income per share:				
Net income	\$ 0.53	\$ 0.54	\$ 2.11	\$ 2.15
Diluted weighted average common shares outstanding	15,141	14,979	15,068	15,116

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

	<b>December 31,</b>	<b>December 31,</b>
<b>ASSETS</b>	<b>2017</b>	<b>2016</b>
Current assets:		
Cash and cash equivalents	\$ 133,256	\$ 104,261
Investments	24,000	20,500
Accounts receivable, net of reserves of \$1,914 and \$194 at December 31, 2017 and December 31, 2016, respectively	23,825	27,598
Inventories, net	22,035	15,983
Prepaid expenses and other current assets	3,211	2,098
Total current assets	<u>206,327</u>	<u>170,440</u>
Property and equipment, net	56,183	52,296
Other long-term assets	1,254	69
Intangible assets, net	10,635	10,227
Goodwill	8,218	7,214
Total assets	<u>\$ 282,617</u>	<u>\$ 240,246</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,747	\$ 2,303
Accrued expenses and other current liabilities	6,326	6,496
Total current liabilities	<u>13,073</u>	<u>8,799</u>
Other long-term liabilities	660	2,126
Deferred tax liability	5,393	6,548
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,250 shares authorized, no shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	-	-
Common stock, \$0.01 par value; 60,000 shares authorized, 14,688 and 14,627 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	147	146
Additional paid-in-capital	68,617	61,735
Accumulated other comprehensive loss	(4,784)	(7,317)
Retained earnings	199,511	168,209
Total stockholders' equity	<u>263,491</u>	<u>222,773</u>
Total liabilities and stockholders' equity	<u>\$ 282,617</u>	<u>\$ 240,246</u>

**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,			
	2017	%	2016	%	2017	%	2016	%
Orthobiologics	\$ 25,131	87%	\$ 24,376	86%	\$ 93,816	87%	\$ 89,695	87%
Surgical	867	3%	1,590	6%	5,262	5%	5,427	5%
Dermal	1,519	5%	1,114	4%	2,755	3%	2,759	3%
Other	1,367	5%	1,216	4%	5,950	5%	5,051	5%
Product Revenue	<u>\$ 28,884</u>	<u>100%</u>	<u>\$ 28,296</u>	<u>100%</u>	<u>\$ 107,783</u>	<u>100%</u>	<u>\$ 102,932</u>	<u>100%</u>
Product Gross Profit	\$ 20,168		\$ 20,757		\$ 80,419		\$ 78,905	
Product Gross Margin	70%		73%		75%		77%	

**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,			
	2017	%	2016	%	2017	%	2016	%
United States	\$ 23,783	82%	\$ 22,940	81%	\$ 87,290	81%	\$ 83,972	82%
Europe	2,692	9%	2,696	10%	12,435	12%	10,953	10%
Other	2,409	9%	2,660	9%	8,058	7%	8,007	8%
Product Revenue	<u>\$ 28,884</u>	<u>100%</u>	<u>\$ 28,296</u>	<u>100%</u>	<u>\$ 107,783</u>	<u>100%</u>	<u>\$ 102,932</u>	<u>100%</u>

CONTACT:  
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