ANIKA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 07/26/17 for the Period Ending 07/26/17

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

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): July 26, 2017

Anika Therapeutics, Inc.

(*Exact name of registrant as specified in its charter*)

Massachusetts	000-21326	04-3145961
(State or other jurisdiction of incorporation or organization)	*Commission file number*	*(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. □

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 July 26, 2017, Anika Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended June 30, 2017. 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 July 26, 2017.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

Anika Therapeutics, Inc.

Dated: July 26, 2017

By: /s/ Sylvia Cheung

Sylvia Cheung

Chief Financial Officer

Exhibit Index

99.1	Press Release of Anika Therapeutics, Inc. dated July 26, 2017.

Exhibit 99.1

Anika Reports Strong Second Quarter 2017 Financial Results

MONOVISC U.S. End-User Sales Exceeded $100 Million at an Accelerated Pace

CINGAL Phase III Clinical Trial Achieved Rapid Advancements

BEDFORD, Mass.--(BUSINESS WIRE)--July 26, 2017--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 second quarter ended June 30, 2017, along with business progress in the period.

"Anika delivered strong double-digit revenue and earnings growth in the second quarter of 2017, driven primarily by very robust demand for MONOVISC worldwide," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "MONOVISC U.S. end-user revenue increased 56% year-over-year in the second quarter, and exceeded our expectations for the quarter. We also made significant progress executing our global expansion strategy, as evidenced by international Orthobiologics revenue growth of 50% year-over-year for the quarter. Additionally, CINGAL continued to gain momentum in Canada and Europe, and we made considerable progress enrolling patients in our supplemental Phase III trial of CINGAL during the quarter."

Second Quarter Financial Results

- Total revenue for the second quarter of 2017 increased 26% year-over-year to $33.5 million, compared to $26.6 million for the second quarter of 2016. Total revenue for the second quarter of 2017 included $5.0 million in milestone revenue earned 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 for the second quarter of 2017 increased 7% year-over-year to $28.3 million, compared to $26.6 million for the second quarter of 2016. Worldwide Orthobiologics revenue grew 5% year-over-year in the second quarter of 2017. The main driver of this product revenue growth was an increase in global MONOVISC revenue of 22% year-over-year in the second quarter of 2017, which was partially offset by a decline in ORTHOVISC revenue in the same period.
- International Orthobiologics revenue increased 50% year-over-year for the second quarter of 2017, due primarily to the global expansion of MONOVISC, as well as growth of CINGAL in Canada and Europe. Domestically, ORTHOVISC and MONOVISC continue to maintain a combined market leading position.
- Total operating expenses for the second quarter of 2017 were $15.7 million, compared to $13.1 million for the second quarter of 2016. The increase in total operating expenses was due primarily to higher research and development spending required to advance the Company's product pipeline, expanded operational efforts, and increased professional service fees.
- Net income for the second quarter of 2017 increased 32% to $11.4 million, or $0.76 per diluted share, compared to $8.6 million, or $0.57 per diluted share, for the second quarter of 2016. The increase in net income was due primarily to an increase in total revenue.

Recent Business Highlights

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

- Completing all site qualification activities and enrolling approximately 30 patients for the Company's supplemental Phase III trial evaluating the efficacy and safety of CINGAL, its novel HA-corticosteroid combination viscosupplement for the treatment of symptoms associated with osteoarthritis (OA) of the knee. The Company expects to complete patient enrollment by the end of 2017.
- Publishing results from the Company's original Phase III trial of CINGAL in the peer-reviewed journal Cartilage. The data demonstrated that CINGAL provided improved immediate and short term pain relief after injection as compared to HA alone, and enhanced relief from OA-related pain, stiffness and function through 26 weeks as compared to saline.
- Receiving regulatory approval for MONOVISC in India for the treatment of pain associated with osteoarthritis of all human synovial joints. The Company plans to expand into India, Australia, and New Zealand over the next six to nine months.
- Advancing its product pipeline with continued progress on enrolling patients in the FastTRACK Phase III HYALOFAST Study for cartilage repair, as well as the Phase III MONOVISC study for the treatment of osteoarthritis pain in the hip.
- Progressing the consolidation of the Company's global manufacturing operations at Anika's Bedford, Massachusetts corporate headquarters. The Company also opened its new European headquarters and surgical training center in Padova, Italy.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights tomorrow, Thursday, July 27 th 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 . 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 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 .

Forward-Looking Statements

The statements made in the last sentence of the first bullet point and the last sentence of third bullet point in the section captioned "Recent Business Highlights" 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 patient enrollment expectations with regard to the Company's supplemental Cingal Phase III clinical trial and the Company's international expansion expectations in the near future. 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.

Anika Therapeutics, Inc. and Subsidiaries
Condensed 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,	
	2017	**2016**	**2017**	**2016**
Product revenue	$ 28,340	$ 26,575	$ 51,721	$ 48,853
Licensing, milestone and contract revenue	5,122	6	5,127	11
Total revenue	33,462	26,581	56,848	48,864
Operating expenses:				
Cost of product revenue	6,315	6,065	12,398	11,490
Research and development	4,449	2,792	8,679	4,951
Selling, general and administrative	4,972	4,255	10,039	8,245
Total operating expenses	15,736	13,112	31,116	24,686
Income from operations	17,726	13,469	25,732	24,178
Interest income, net	16	49	74	121
Income before income taxes	17,742	13,518	25,806	24,299
Provision for income taxes	6,373	4,903	8,944	8,789
Net income	$ 11,369	$ 8,615	$ 16,862	$ 15,510
Basic net income per share:				
Net income	$ 0.78	$ 0.59	$ 1.16	$ 1.05
Basic weighted average common shares outstanding	14,588	14,679	14,582	14,778
Diluted net income per share:				
Net income	$ 0.76	$ 0.57	$ 1.12	$ 1.02
Diluted weighted average common shares outstanding	15,044	15,111	15,046	15,210

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

ASSETS	June 30, 2017	December 31, 2016
Current assets:		
Cash and cash equivalents	$117,874	$ 104,261
Investments	25,000	20,500
Accounts receivable, net of reserves of $210 and $194 at June 30, 2017 and December 31, 2016, respectively	30,450	27,598
Inventories, net	17,584	15,983
Prepaid expenses and other current assets	1,973	2,098
Total current assets	192,881	170,440
Property and equipment, net	52,272	52,296
Long-term deposits and other	1,389	69
Intangible assets, net	10,626	10,227
Goodwill	7,836	7,214
Total assets	$265,004	$ 240,246
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,465	$ 2,303
Accrued expenses and other current liabilities	7,976	6,496
Total current liabilities	13,441	8,799
Other long-term liabilities	422	2,126
Deferred tax liability	7,003	6,548
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.01 par value; 1,250 shares authorized, no shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	-
Common stock, $.01 par value; 60,000 authorized, 14,658 and 14,627 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	146	146
Additional paid-in-capital	65,171	61,735
Accumulated other comprehensive loss	(5,736)	(7,317)
Retained earnings	184,557	168,209
Total stockholders' equity	244,138	222,773
Total liabilities and stockholders' equity	$265,004	$ 240,246

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:	**2017**	**%**	**2016**	**%**	**2017**	**%**	**2016**	**%**
Orthobiologics	$ 24,468	86%	$ 23,304	88%	$ 44,695	86%	$ 42,891	88%
Surgical	1,335	5%	1,433	5%	2,631	5%	2,751	6%
Dermal	453	2%	582	2%	878	2%	963	2%
Other	2,084	7%	1,256	5%	3,517	7%	2,248	4%
Product Revenue	$ 28,340	100%	$ 26,575	100%	$ 51,721	100%	$ 48,853	100%
Product Gross Profit	$ 22,025		$ 20,510		$ 39,323		$ 37,363	
Product Gross Margin	78%		77%		76%		76%	

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

	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2017	**%**	**2016**	**%**	**2017**	**%**	**2016**	%
Geographic Region:								
United States	$ 22,331	79%	$ 21,895	82%	$ 41,261	80%	$ 39,906	82%
Europe	4,060	14%	2,977	11%	6,889	13%	5,542	11%
Other	1,949	7%	1,703	7%	3,571	7%	3,405	7%
Product Revenue	$ 28,340	100%	$ 26,575	100%	$ 51,721	100%	$ 48,853	100%

CONTACT:
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