
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 25, 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.

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 25, 2018, Anika Therapeutics, Inc. issued a press release announcing its financial results for the second quarter and six months ended June 30, 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 July 25, 2018.

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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 25, 2018

By: /s/ Sylvia Cheung
Sylvia Cheung
Chief Financial Officer

Exhibit Index

99.1 [Press Release of Anika Therapeutics, Inc. dated July 25, 2018.](#)

Anika Reports Second Quarter 2018 Financial Results

Solid Top and Bottom Line Performance with 8% Product Revenue Growth and \$0.68 Diluted EPS

New Leadership Added to Optimize Commercial Reach and Operating Efficiency

Multiple Initiatives Ongoing to Gain U.S. Regulatory Approval of CINGAL

BEDFORD, Mass.--(BUSINESS WIRE)--July 25, 2018--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, 2018, along with business progress in the period.

"Anika's strategic initiatives in the second quarter were focused on opportunities to accelerate revenue growth in 2019 and beyond," said Joseph Darling, President and Chief Executive Officer of Anika Therapeutics. "We strengthened our senior leadership team, increased our focus on strategic M&A, and began executing on multiple strategies to gain U.S. regulatory approval of CINGAL. Bringing CINGAL to U.S. patients and physicians remains one of Anika's top strategic priorities. We are committed to both maximizing our current business opportunities and pursuing new growth initiatives to create near- and long-term value for shareholders."

Second Quarter Financial Results

- Product revenue increased 8% year-over-year in the second quarter of 2018, due primarily to higher MONOVISC revenue in the U.S. Global MONOVISC revenue increased 26% year-over-year in the second quarter of 2018.
 - U.S. Viscosupplementation revenue increased \$2.3 million year-over-year for the second quarter of 2018. International Viscosupplementation revenue decreased \$0.7 million year-over-year for the second quarter of 2018, due primarily to the timing of orders. Domestically, ORTHOVISC and MONOVISC maintained the number one position in the combined multi- and single-injection segments in the second quarter of 2018.
 - Total revenue for the second quarter of 2018 was \$30.5 million, compared to \$33.5 million for the second quarter of 2017. The year-over-year decline was due to the achievement of \$5.0 million of milestone revenue in the second quarter of 2017, as a result of MONOVISC reaching \$100 million in U.S. end-user sales within a consecutive 12-month period.
 - Total operating expenses for the second quarter of 2018 were \$19.3 million, compared to \$15.7 million for the second quarter of 2017. The increase in total operating expenses was due primarily to product revenue growth, increased personnel costs, and expanded worldwide commercial initiatives.
 - Net income for the second quarter of 2018 was \$10.1 million, or \$0.68 per diluted share, compared to \$11.4 million, or \$0.76 per diluted share, for the second quarter of 2017. The decline in net income was due primarily to the increase in operating expenses previously discussed.
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Recent Business Highlights

- Announced that initial top-line results for the CINGAL 16-02 clinical trial, an active-comparator Phase III study conducted to support U.S. approval, did not reach statistical significance, although it did maintain the durability of strong pain relief throughout the 26 weeks, consistently demonstrating the long-term benefits of CINGAL. The magnitude of pain reduction demonstrated incremental improvement compared to the previous CINGAL Phase III study, and the duration of patient improvement after CINGAL injection was maintained near peak levels throughout the 26-week study. Anika has engaged external regulatory and legal experts to assist in the strategic approach for seeking CINGAL approval in the U.S. market. Anika remains fully committed to working closely with regulators to gain U.S. approval of CINGAL.
- Strengthened the senior leadership management team with the newly created position of Vice President of International Sales based in Europe to maximize sales impact and optimize the Company's commercial reach in our foreign markets.
- Added a new Vice President of Operations to senior leadership team to focus on operation efficiency and margin improvements.
- Redirected internal efforts of Chief Technology and Strategy Officer with spear-heading the assessment of strategic M&A opportunities.
- Completed the Company's \$30 million accelerated share repurchase program in July, under which Anika repurchased approximately 800,000 shares of its outstanding common stock.

Full Year 2018 Revised Corporate Outlook

Based on currently available information, the Company revised its guidance for the full year of 2018. Anika currently does not expect licensing, milestone and contract revenue of \$5.0 million in 2018. The Company continues to anticipate product revenue to be flat for the full year of 2018. The Company continues to expect that it will resume the shipment of products that were the subject of the previously-disclosed voluntary recall by the end of this year. Total operating expenses are now expected to be in the low \$90 million range for the full year of 2018, adjusted for the reduction of CINGAL pre-launch marketing expenses.

Conference Call Information

Anika's management will hold a conference call and webcast to discuss its financial results and business highlights tomorrow, Thursday, July 26 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 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[®], 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 section captioned "Full Year 2018 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 2018 revenue and total operating expense expectations and to the Company's timeline to resume shipping of products that were the subject of the previously-disclosed voluntary recall. 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
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,	
	2018	2017	2018	2017
Product revenue	\$ 30,542	\$ 28,340	\$ 51,800	\$ 51,721
Licensing, milestone and contract revenue	6	5,122	12	5,127
Total revenue	<u>30,548</u>	<u>33,462</u>	<u>51,812</u>	<u>56,848</u>
Operating expenses:				
Cost of product revenue	8,152	6,315	15,996	12,398
Research and development	4,733	4,449	9,895	8,679
Selling, general and administrative	6,417	4,972	22,507	10,039
Total operating expenses	<u>19,302</u>	<u>15,736</u>	<u>48,398</u>	<u>31,116</u>
Income from operations	11,246	17,726	3,414	25,732
Interest and other income, net	290	16	385	74
Income before income taxes	11,536	17,742	3,799	25,806
Provision for income taxes	1,445	6,373	394	8,944
Net income	<u>\$ 10,091</u>	<u>\$ 11,369</u>	<u>\$ 3,405</u>	<u>\$ 16,862</u>
Basic net income per share:				
Net income	\$ 0.69	\$ 0.78	\$ 0.23	\$ 1.16
Basic weighted average common shares outstanding	14,652	14,588	14,666	14,582
Diluted net income per share:				
Net income	\$ 0.68	\$ 0.76	\$ 0.23	\$ 1.12
Diluted weighted average common shares outstanding	14,915	15,044	15,045	15,046

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

	June 30,	December 31,
ASSETS	2018	2017
Current assets:		
Cash and cash equivalents	\$ 126,047	\$ 133,256
Investments	13,250	24,000
Accounts receivable	23,389	23,825
Inventories, net	24,060	22,035
Prepaid expenses and other current assets	4,245	3,211
Total current assets	<u>190,991</u>	<u>206,327</u>
Property and equipment, net	55,377	56,183
Other long-term assets	1,157	1,254
Intangible assets, net	9,876	10,635
Goodwill	8,013	8,218
Total assets	<u>\$ 265,414</u>	<u>\$ 282,617</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,074	\$ 6,747
Accrued expenses and other current liabilities	7,459	6,326
Total current liabilities	<u>12,533</u>	<u>13,073</u>
Other long-term liabilities	882	660
Deferred tax liability	5,396	5,393
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,250 shares authorized, no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	-	-
Common stock, \$0.01 par value; 90,000 shares authorized, 14,584 and 14,688 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	146	147
Additional paid-in-capital	48,656	68,617
Accumulated other comprehensive loss	(5,115)	(4,784)
Retained earnings	202,916	199,511
Total stockholders' equity	<u>246,603</u>	<u>263,491</u>
Total liabilities and stockholders' equity	<u>\$ 265,414</u>	<u>\$ 282,617</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 June 30,				For the Six Months Ended June 30,			
	2018	%	2017	%	2018	%	2017	%
Orthobiologics	\$ 26,192	86%	\$ 24,468	86%	\$ 45,681	88%	\$ 44,695	86%
Surgical	1,263	4%	1,335	5%	2,509	5%	2,631	5%
Dermal	623	2%	453	2%	83	0%	878	2%
Other	2,464	8%	2,084	7%	3,527	7%	3,517	7%
Product Revenue	\$ 30,542	100%	\$ 28,340	100%	\$ 51,800	100%	\$ 51,721	100%
Product Gross Profit	\$ 22,390		\$ 22,025		\$ 35,803		\$ 39,323	
Product Gross Margin	73%		78%		69%		76%	

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

Geographic Region:	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2018	%	2017	%	2018	%	2017	%
United States	\$ 24,773	81%	\$ 22,331	79%	\$ 41,682	81%	\$ 41,261	80%
Europe	3,498	11%	4,060	14%	5,889	11%	6,889	13%
Other	2,271	8%	1,949	7%	4,229	8%	3,571	7%
Product Revenue	\$ 30,542	100%	\$ 28,340	100%	\$ 51,800	100%	\$ 51,721	100%

CONTACT:
Anika Therapeutics, Inc.
Joseph Darling, President & CEO
Sylvia Cheung, CFO
Tel: 781-457-9000