Anika Therapeutics, Inc.
Form 10-Q
May 10, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2018

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

For the transition period from to

Commission File Number 000-21326

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
32 Wiggins Avenue, Bedford, Massachusetts	**01730**
(Address of Principal Executive Offices)	(Zip Code)

(781) 457-9000

(Registrant's Telephone Number, Including Area Code)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company	Emerging growth company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

APPLICABLE ONLY TO CORPORATE ISSUERS:

As of May 3, 2018, there were 14,745,152 outstanding shares of Common Stock, par value $.01 per share.

ANIKA THERAPEUTICS, INC.

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References in this Quarterly Report on Form 10-Q to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands, except per share data)

(unaudited)

ASSETS	March 31, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	$141,797	$133,256
Investments	21,250	24,000
Accounts receivable, net of reserves of $2,180 and $1,914 at March 31, 2018 and December 31, 2017, respectively	18,289	23,825
Inventories, net	22,770	22,035
Prepaid expenses and other current assets	4,081	3,211
Total current assets	208,187	206,327
Property and equipment, net	55,772	56,183
Other long-term assets	1,247	1,254
Intangible assets, net	10,678	10,635
Goodwill	8,452	8,218
Total assets	$284,336	$282,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$6,159	$6,747
Accrued expenses and other current liabilities	7,963	6,326
Total current liabilities	14,122	13,073
Other long-term liabilities	1,150	660
Deferred tax liability	5,298	5,393
Commitments and contingencies (Note 12)		

Stockholders' equity:		
Preferred stock, $.01 par value; 1,250 shares authorized, no shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Common stock, $.01 par value; 60,000 shares authorized, 14,745 and 14,688 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	147	147
Additional paid-in-capital	74,958	68,617
Accumulated other comprehensive loss	(4,164)	(4,784)
Retained earnings	192,825	199,511
Total stockholders' equity	263,766	263,491
Total liabilities and stockholders' equity	$284,336	$282,617

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Product revenue	$21,258	$23,381
Licensing, milestone and contract revenue	6	5
Total revenue	21,264	23,386
Operating expenses:		
Cost of product revenue	7,845	6,083
Research & development	5,161	4,230
Selling, general & administrative	16,090	5,067
Total operating expenses	29,096	15,380
Income (loss) from operations	(7,832)	8,006
Interest and other income, net	95	58
Income (loss) before income taxes	(7,737)	8,064
Provision for (benefit from) income taxes	(1,051)	2,571
Net income (loss)	$(6,686)	$5,493
Basic net income (loss) per share:		
Net income (loss)	$(0.46)	$0.38
Basic weighted average common shares outstanding	14,679	14,576
Diluted net income (loss) per share:		
Net income (loss)	$(0.46)	$0.37
Diluted weighted average common shares outstanding	14,679	15,043
Net income (loss)	$(6,686)	$5,493
Foreign currency translation adjustment	620	292
Comprehensive income (loss)	$(6,066)	$5,785

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	$ (6,686)	$ 5,493
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	1,473	1,014
Loss on disposal of fixed assets	142	-
Stock-based compensation expense	7,565	1,182
Deferred income taxes	(75)	385
Provision for inventory	3,246	264
Changes in operating assets and liabilities:		
Accounts receivable	5,730	6,601
Inventories	(3,924)	(431)
Prepaid expenses, other current and long-term assets	509	744
Accounts payable	(180)	2,020
Accrued expenses, other current and long-term liabilities	3,270	(1,807)
Income taxes	(1,478)	(5)
Net cash provided by operating activities	9,592	15,460
Cash flows from investing activities:		
Proceeds from maturity of investments	15,250	12,500
Purchase of investments	(12,500)	(11,250)
Purchase of property and equipment	(2,543)	(1,675)
Net cash provided by (used in) investing activities	207	(425)
Cash flows from financing activities:		
Cash paid for tax withheld on vested restricted stock awards	(1,735)	-
Proceeds from exercise of equity awards	512	41
Net cash (used in) provided by financing activities	(1,223)	41
Exchange rate impact on cash	(35)	31
Increase in cash and cash equivalents	8,541	15,107
Cash and cash equivalents at beginning of period	133,256	104,261
Cash and cash equivalents at end of period	$ 141,797	$ 119,368
Supplemental disclosure of cash flow information:		

Non-cash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 207	$ 2,081

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ANIKA THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share amounts or as otherwise noted)

(**unaudited**)

1. Nature of Business

Anika Therapeutics, Inc. (the "Company") is a global, integrated orthopedic and regenerative medicines company 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 products based on the Company's proprietary Hyaluronic Acid ("HA") technology. The Company'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.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with U.S. Food and Drug Administration ("FDA") and foreign regulations and approval requirements, as well as the ability to grow the Company's business through appropriate commercial strategies.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and in accordance with accounting principles generally accepted in the United States ("US GAAP"). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with US GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. The December 31, 2017 balances reported herein are derived from the audited consolidated financial statements. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the condensed consolidated financial position of the Company as of March 31, 2018, the results of its operations for the three-month periods ended March 31, 2018 and 2017, and cash flows for the three-month periods ended March 31,

2018 and 2017.

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with the Company's annual financial statements filed with its Annual Report on Form 10-K for the year ended December 31, 2017. The results of operations for the three-month period ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which requires an entity to recognize revenue for the transfer of goods or services equal to the amount that it expects to be entitled in exchange for those goods or services. ASU 2014-09 supersedes most previous revenue recognition guidance and is effective for interim and annual reporting periods beginning within 2018. The Company adopted the new guidance as of January 1, 2018 using the modified retrospective adoption method. See Note 3 for further details.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). ASU 2016-02 amends existing leasing accounting requirements. The most significant change will result in the recognition of lease assets and lease liabilities by lessees for virtually all leases. The new guidance will also require significant additional disclosures about the amount, timing, and uncertainty of cash flows from leases. ASU 2016-02 is effective for fiscal years and interim periods beginning after December 15, 2018. Upon adoption, entities are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted, and a number of optional practical expedients may be elected to simplify the impact of adoption. The Company is assessing ASU 2016-02 and the impact that adopting this new accounting standard will have on its consolidated financial statements and footnote disclosures.

3. Revenue

The Company adopted the guidance in the FASB's Accounting Standards Codification (ASC) Revenue from Contracts with Customers (ASC 606) using the modified retrospective method effective January 1, 2018. The adoption of ASC 606 was applied to all contracts not completed as of the date of adoption. The adoption did not have a material impact on the amount and timing of revenue recognized in the condensed consolidated financial statements.

Pursuant to ASC 606, revenue is recognized by the Company when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that the Company expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct or distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Product Revenues

The Company sells its products principally to a limited number of distributors. The Company's distributors subsequently resell the products to their customers, which includes sub-distributors and health care providers, among others. The Company recognizes revenue from product sales when the distributor obtains control of the Company's product, which typically occurs upon shipment to the distributor. The Company's payment terms are consistent with prevailing practice in the respective markets in which the Company does business. Distributors make payments based on contractually stated contract terms. The Company's contracts with customers do not provide a right of return, unless certain product quality standards are not met.

To identify variable considerations and determine the transaction price, the Company has reviewed its standard terms and conditions and its customary business practices. Volume based discounts with tiered pricing are generally prospective in nature. These prospective discounts together with any free-of-charge sample units offered are evaluated as potential material rights. If the discounts or free of charge sample units are considered significant in the context of the contract, revenue deferral may be required.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or after performance, resulting in a significant financing component. Applying the practical expedient in paragraph ASC 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less.

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The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. As of March 31, 2018, deferred revenue was immaterial.

Generally, the contracts contain Free on Board (FOB) shipping point or Ex-Works terms where the customer pays the shipping company directly for all shipping and handling costs. In those contracts in which the Company pays for the shipping and handling, the associated costs are generally recorded along with the product sale at the time of shipment in cost of product revenue when control over the products has transferred to the customer. The Company does not collect sales tax on its product sales. Value add and other taxes collected by the Company concurrently with revenue-producing activities are excluded from revenue. The Company recognizes the incremental costs of obtaining contracts as an expense when incurred as the amortization period of the assets that the Company otherwise would have recognized is one year or less in accordance with the practical expedient in paragraph ASC 340-40-25-4. These costs are included in selling, general and administrative expenses.

Included as a component of product revenue is sales-based royalty revenue, which represents the utilization of our intellectual property licensed by our commercial partners. The Company does not have future performance obligations under these license arrangements. The license is deemed to be the predominant item to which the royalties relate, and thus the constraints on variable consideration are applied. The Company records royalty revenues based on estimated net sales of licensed products as reported to us by our commercial partners. Differences between actual and estimated royalty revenues have not been material and are typically adjusted in the following quarter when the actual amounts are known.

License, Milestone and Contract Revenues

The Company has agreements with DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics, Inc. ("Mitek") that include the grant of certain licenses, performance of development services, and supply of product. Revenues from the agreements with Mitek represent 76% of total Company revenues in the first quarter of 2018. The Company has agreements with other customers that may include the delivery of a license and supply of product. The adoption of ASC 606 did not impact the accounting for these agreements.

The agreements with Mitek include variable consideration such as contingent development and regulatory milestones, sales-based milestones, and royalties. The Company completed the performance obligations related to granted licenses and development services under these agreements in prior years. Agreements that include a promise for future supply of product at the customer's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Variable consideration is included in the transaction price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with the variable consideration is subsequently resolved. Sales-based milestones and royalties for these arrangements are excluded from this assessment and are only recognized when the later of the underlying sale occurs or the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied). Future revenue from sales-based or regulatory milestones will be subject to the constraints around variable consideration and will generally be recognized at the time the milestone is achieved. Revenue from sales-based royalties is included in product revenues as discussed above.

As a result of applying the modified retrospective method to adopt the new revenue guidance, there was no cumulative effect to balance sheet accounts as of the adoption date.

The following tables provide the disaggregated revenue by primary geographical market and major product group. Product revenue by product group is as follows:

	Three Months Ended March 31,	
	2018	2017
Orthobiologics	$ 19,489	$ 20,227
Surgical	1,245	1,296
Dermal	(539)	425
Other	1,063	1,433
Product Revenue	$ 21,258	$ 23,381

Total revenue by geographic location and as a percentage of overall total revenue for the three-month periods ended March 31, 2018 and 2017 are as follows:

	Three Months Ended March 31,					
	2018			2017		
	Total Revenue	Percentage of Revenue		Total Revenue	Percentage of Revenue	
Geographic Location:						
United States	$16,910	80	%	$18,930	81	%
Europe	2,391	11	%	2,829	12	%
Other	1,963	9	%	1,627	7	%
Total Revenue	$21,264	100	%	$23,386	100	%

On May 2, 2018, the Company publicly disclosed a voluntary recall of certain lots of its HYAFF-based products, HYALOFAST, HYALOGRAFT C, and HYALOMATRIX. The Company initiated the recall after internal quality testing, which indicated that the products were at risk of not maintaining certain measures throughout their entire shelf life. While there is no indication of any safety or efficacy issue related to the products at this time, the Company remains committed to the highest standards of quality and is removing the products from the field as a precautionary measure. The Company recorded a revenue reserve for this voluntary recall of $1.1 million of which $0.9 million was related to revenue recorded in prior periods and is recorded in accrued expenses and $0.2 million which is recorded against outstanding receivables. The revenue reserves impacted Dermal and Orthobiologics product groups and all geographic locations.

4. Investments

All of the Company’s investments are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss), net of related income taxes. The Company held bank certificates of deposit of $21.3 million and $24.0 million at March 31, 2018 and December 31, 2017, respectively. There were no unrealized gains or losses on the Company’s available-for-sale securities at March 31, 2018 or December 31, 2017.

5. Fair Value Measurements

The Company’s investments are all classified within Levels 1 and 2 of the fair value hierarchy. The Company’s investments classified within Level 1 of the fair value hierarchy are valued based on quoted prices in active markets. Level 2 investments are based on matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk. For cash and cash equivalents, current receivables, accounts

payable, and interest accrual, the carrying amounts approximate fair value because of the short maturity of these instruments, and therefore fair value information is not included in the table below.

The fair value hierarchy of the Company's cash equivalents and investments at fair value is as follows:

		Fair Value Measurements at Reporting Date Using		
	March 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$6,504	$ 6,504	$ -	$ -
Bank certificates of deposit	2,750	-	2,750	-
Total cash equivalents	$9,254	$ 6,504	$ 2,750	$ -
Investments:				
Bank certificates of deposit	$21,250	$ -	$ 21,250	$ -

		Fair Value Measurements at Reporting Date Using		
	December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market				