

Anika Therapeutics, Inc.
Form 10-Q
October 26, 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 September 30, 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)

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Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

04-3145961

(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 every Interactive Data File required to be submitted 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 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	Smaller reporting company	Emerging growth company
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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:

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As of October 18, 2018, there were 14,211,457 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.

ANIKA, ANIKA THERAPEUTICS, CINGAL, HYAFF, MONOVISC, and ORTHOVISC are our registered trademarks. This Quarterly Report on Form 10-Q also contains registered marks, trademarks, and trade names that are the property of other companies and licensed to us.

PART I: FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****Anika Therapeutics, Inc. and Subsidiaries****Condensed Consolidated Balance Sheets****(in thousands, except share data and per share data)****(unaudited)**

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$81,825	\$133,256
Investments	67,186	24,000
Accounts receivable, net of reserves of \$1,771 and \$1,914 at September 30, 2018 and December 31, 2017, respectively	20,771	23,825
Inventories, net	23,828	22,035
Prepaid expenses and other current assets	1,981	3,211
Total current assets	195,591	206,327
Property and equipment, net	55,041	56,183
Other long-term assets	1,109	1,254
Intangible assets, net	9,564	10,635
Goodwill	7,959	8,218
Total assets	\$269,264	\$282,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,462	\$6,747
Accrued expenses and other current liabilities	6,843	6,326
Total current liabilities	9,305	13,073
Other long-term liabilities	574	660
Deferred tax liability	4,120	5,393
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250 shares authorized, no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Common stock, \$.01 par value; 90,000 and 60,000 shares authorized, 14,211 and 14,688 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	142	147
Additional paid-in-capital	49,836	68,617
Accumulated other comprehensive loss	(5,228) (4,784

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Retained earnings	210,515	199,511
Total stockholders' equity	255,265	263,491
Total liabilities and stockholders' equity	\$269,264	\$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****(in thousands, except per share data)****(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product revenue	\$26,781	\$27,178	\$78,581	\$78,899
Licensing, milestone and contract revenue	6	6	18	5,133
Total revenue	26,787	27,184	78,599	84,032
Operating expenses:				
Cost of product revenue	8,282	6,250	24,279	18,648
Research & development	4,232	5,842	14,126	14,521
Selling, general & administrative	5,700	4,823	28,207	14,862
Total operating expenses	18,214	16,915	66,612	48,031
Income from operations	8,573	10,269	11,987	36,001
Interest and other income, net	522	261	907	335
Income before income taxes	9,095	10,530	12,894	36,336
Provision for income taxes	1,496	3,643	1,890	12,587
Net income	\$7,599	\$6,887	\$11,004	\$23,749
Basic net income per share:				
Net income	\$0.53	\$0.47	\$0.76	\$1.63
Basic weighted average common shares outstanding	14,237	14,579	14,524	14,572
Diluted net income per share:				
Net income	\$0.53	\$0.46	\$0.74	\$1.58
Diluted weighted average common shares outstanding	14,377	15,115	14,820	15,065
Net income	\$7,599	\$6,887	\$11,004	\$23,749
Foreign currency translation adjustment	(113)	690	(444)	2,270
Comprehensive income	\$7,486	\$7,577	\$10,560	\$26,019

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)**

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net income	\$ 11,004	\$ 23,749
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,433	3,224
Loss on disposal of fixed assets	172	-
Stock-based compensation expense	10,064	3,940
Deferred income taxes	(1,205)	943
Provision for doubtful accounts	(87)	(1)
Provision for inventory	4,073	609
Changes in operating assets and liabilities:		
Accounts receivable	3,136	4,388
Inventories	(5,891)	(4,668)
Prepaid expenses, other current and long-term assets	1,304	(922)
Accounts payable	(2,449)	2,030
Accrued expenses, other current and long-term liabilities	509	(106)
Income taxes	(158)	645
Net cash provided by operating activities	24,905	33,831
Cash flows from investing activities:		
Proceeds from maturity of investments	34,500	31,250
Purchase of investments	(77,683)	(36,500)
Purchase of property and equipment	(4,493)	(6,506)
Net cash (used in) investing activities	(47,676)	(11,756)
Cash flows from financing activities:		
Repurchases of common stock	(30,000)	-
Cash paid for tax withheld on vested restricted stock awards	(1,735)	-
Proceeds from exercise of equity awards	2,886	310
Net cash (used in) provided by financing activities	(28,849)	310
Exchange rate impact on cash	189	314
(Decrease) Increase in cash and cash equivalents	(51,431)	22,699
Cash and cash equivalents at beginning of period	133,256	104,261

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Cash and cash equivalents at end of period	\$81,825	\$126,960
Supplemental disclosure of cash flow information:		
Non-cash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$197	\$1,208

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 its 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 September 30, 2018, the results of its operations for the three- and nine-month periods ended September 30, 2018 and 2017, and cash flows for the nine-month periods ended September 30, 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- and nine-month periods ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018.

At the Company's annual stockholders' meeting on May 31, 2018, the Company's stockholders approved an increase in the number of shares of common stock that the Company is authorized to issue from 60 million to 90 million and ratified a change in the Company's state of incorporation from the Commonwealth of Massachusetts to the State of Delaware, pursuant to a plan of domestication. The Company became a Delaware corporation with the authorization to issue up to 90 million shares of its common stock on June 6, 2018. Upon its domestication in Delaware, the affairs of the Company became subject to the Delaware General Corporation Law, the Company implemented a new certificate of incorporation and new bylaws, and each previously outstanding share of the Company's common stock as a Massachusetts corporation (Anika Massachusetts) converted into an outstanding share of common stock of the Company as a Delaware corporation (Anika Delaware). The domestication was a tax-free reorganization under the U.S. Internal Revenue Code, and it did not affect the Company's business operations.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which 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 has commenced work to assess ASU 2016-02 and the impact that adopting this new accounting standard will have on its consolidated financial statements and footnote disclosures. The Company anticipates recognition of material additional assets and corresponding liabilities related to the Company's leases on its consolidated balance sheet.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software* (Subtopic 350-40), which amends ASU No. 2015-05, *Customers Accounting for Fees in a Cloud Computing Agreement*, to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The most significant change will align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal-use software license. Accordingly, the amendments in ASU 2018-15 require an entity in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period for all entities. The Company is assessing ASU 2018-15 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. The Company made no adjustments to its previously reported product and total revenue, as those periods continue to be presented in accordance with the Company’s historical accounting practices under Topic 605, *Revenue Recognition*.

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 number of distributors (i.e., its customers) under legally-enforceable, executed contracts. The Company’s distributors subsequently resell the products to 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, in return for agreed-upon, fixed-price consideration. Performance obligations are generally settled quickly after purchase order acceptance; therefore, the

value of unsatisfied performance obligations at the end of any reporting period is generally immaterial.

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 fixed-price contract terms, which are not affected by contingent events that could impact the transaction price. Payment terms fall within the one-year guidance for the practical expedient, which allows the Company to forgo adjustment of the contractual payment amount of consideration for the effects of a significant financing component. The Company's contracts with customers do not customarily provide a right of return, unless certain product quality standards are not met.

To identify variable consideration and determine the transaction price, the Company has reviewed its standard contractual 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 is deferred.

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 September 30, 2018, deferred revenue was \$52 thousand.

Generally, distributor contracts contain Free on Board (FOB) or Ex-Works (EXW) shipping point 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 as it is not applicable. Value-add and other taxes collected by the Company concurrently with revenue-producing activities are excluded from revenue. The Company's general product warranty does not extend beyond an assurance that the product or services delivered will be consistent with stated contractual specifications, which does not create a separate performance obligation. 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 & administrative expenses.

Included as a component of product revenue is sales-based royalty revenue, which represents the utilization of the Company's intellectual property licensed by its commercial partners. The Company does not have future performance obligations under license arrangements as described in more detail below. The license is deemed to be the predominant item to which the royalties relate. The Company records royalty revenues based on estimated net sales of licensed products as reported to us by the Company's 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 73% of total Company revenues for the three- and nine-month periods ended September 30, 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 to occur 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 satisfied (or partially satisfied). This is generally in the same period that the Company’s licensees complete their product sales in their territory, for which the company is contractually entitled to a percentage-based royalty. Revenue from sales-based royalties is included in product revenues as discussed above. 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.

There was no cumulative effect to relevant balance sheet accounts upon adopting the new standard using the modified retrospective method.

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

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2018	
	2017	2018	2017	2018
Orthobiologics	\$24,097	\$23,990	\$69,778	\$68,686

Surgical	1,191	1,765	3,700	4,395
Dermal	80			