

Anika Therapeutics, Inc.
Form 10-Q
October 27, 2017

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, 2017

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
(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 No

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 No

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.

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

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 ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

APPLICABLE ONLY TO CORPORATE ISSUERS:

As of October 17, 2017 there were 14,661,769 outstanding shares of Common Stock, par value \$0.01 per share.

ANIKA THERAPEUTICS, INC.

TABLE OF CONTENTS

	Page
<u>Part I</u> <u>Financial Information</u>	
<u>Item 1.</u> <u>Financial Statements (unaudited):</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2017 and 2016</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016</u>	<u>5</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>6</u>
<u>Item 2.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>14</u>
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>19</u>
<u>Item 4.</u> <u>Controls and Procedures</u>	<u>19</u>
<u>Part II</u> <u>Other Information</u>	
<u>Item 1.</u> <u>Legal Proceedings</u>	<u>20</u>
<u>Item 1A.</u> <u>Risk Factors</u>	<u>20</u>
<u>Item 6.</u> <u>Exhibits</u>	<u>21</u>
<u>Signatures</u>	<u>22</u>

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 per share data)

(unaudited)

ASSETS	September 30, 2017	December 31, 2016
Current assets:		
Cash and cash equivalents	\$ 126,960	\$ 104,261
Investments	25,750	20,500
Accounts receivable, net of reserves of \$217 and \$194 at September 30, 2017 and December 31, 2016, respectively	23,804	27,598
Inventories, net	20,252	15,983
Prepaid expenses and other current assets	2,268	2,098
Total current assets	199,034	170,440
Property and equipment, net	53,973	52,296
Other long-term assets	1,283	69
Intangible assets, net	10,738	10,227
Goodwill	8,104	7,214
Total assets	\$ 273,132	\$ 240,246
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,189	\$ 2,303
Accrued expenses and other current liabilities	6,516	6,496
Total current liabilities	11,705	8,799
Other long-term liabilities	545	2,126
Deferred tax liability	7,593	6,548
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,250 shares authorized, no shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Common stock, \$0.01 par value; 60,000 shares authorized, 14,662 and 14,627 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	146	146
Additional paid-in-capital	66,746	61,735

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

Accumulated other comprehensive loss	(5,047)	(7,317)
Retained earnings	191,444	168,209
Total stockholders' equity	253,289	222,773
Total liabilities and stockholders' equity	\$ 273,132	\$ 240,246

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

3

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,	
	2017	2016	2017	2016
Product revenue	\$ 27,178	\$ 25,783	\$ 78,899	\$ 74,636
Licensing, milestone and contract revenue	6	6	5,133	17
Total revenue	27,184	25,789	84,032	74,653
Operating expenses:				
Cost of product revenue	6,250	4,998	18,648	16,488
Research and development	5,842	2,822	14,521	7,773
Selling, general and administrative	4,823	4,280	14,862	12,525
Total operating expenses	16,915	12,100	48,031	36,786
Income from operations	10,269	13,689	36,001	37,867
Interest income, net	261	93	335	214
Income before income taxes	10,530	13,782	36,336	38,081
Provision for income taxes	3,643	4,830	12,587	13,619
Net income	\$ 6,887	\$ 8,952	\$ 23,749	\$ 24,462
Basic net income per share:				
Net income	\$ 0.47	\$ 0.61	\$ 1.63	\$ 1.66
Basic weighted average common shares outstanding	14,579	14,625	14,572	14,726
Diluted net income per share:				
Net income	\$ 0.46	\$ 0.59	\$ 1.58	\$ 1.61
Diluted weighted average common shares outstanding	15,115	15,077	15,065	15,163
Net income	\$ 6,887	\$ 8,952	\$ 23,749	\$ 24,462
Other comprehensive income:				
Foreign currency translation adjustment	690	310	2,270	548
Comprehensive income	\$ 7,577	\$ 9,262	\$ 26,019	\$ 25,010

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,	2016
	2017	2016
Cash flows from operating activities:		
Net income	\$ 23,749	\$ 24,462
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,224	2,777
Stock-based compensation expense	3,940	2,276
Deferred income taxes	943	(571)
Provision for doubtful accounts	(1)	52
Provision for inventory	609	259
Changes in operating assets and liabilities:		
Accounts receivable	4,388	(104)
Inventories	(4,668)	(3,229)
Prepaid expenses, other current and long-term assets	(922)	355
Accounts payable	2,030	(5,390)
Accrued expenses and other current liabilities	643	1,091
Income taxes	645	(3,496)
Other long-term liabilities	(749)	(104)
Net cash provided by operating activities	33,831	18,378
Cash flows from investing activities:		
Proceeds from maturity of investments	31,250	37,750
Purchase of investments	(36,500)	(32,250)
Purchase of property and equipment	(6,506)	(12,608)
Net cash used in investing activities	(11,756)	(7,108)
Cash flows from financing activities:		
Repurchases of common stock	-	(25,000)
Proceeds from exercise of equity awards	310	988
Net cash provided by (used in) financing activities	310	(24,012)
Exchange rate impact on cash	314	82
Increase (decrease) in cash and cash equivalents	22,699	(12,660)
Cash and cash equivalents at beginning of period	104,261	110,707
Cash and cash equivalents at end of period	\$ 126,960	\$ 98,047
Supplemental disclosure of cash flow information:		
Non-cash investing activities:		

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

Purchases of property and equipment included in accounts payable and accrued expenses	\$ 1,208	\$ 474
Build-to-suit lease agreement	\$ -	\$ 1,825

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 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 cartilage 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, 2016 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, 2017, the results of its operations for the three- and nine-month periods ended September 30, 2017 and 2016, and cash flows for the nine-month periods ended September 30, 2017 and 2016.

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, 2016. The results of operations for the nine-month period ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017. Certain prior period amounts have been reclassified to conform to the current period presentation. This change in classification does not materially affect previously reported cash flows from operations or from financing activities in the Condensed Consolidated Statement of Cash Flows, and had no effect on the previously reported Condensed Consolidated Statement of Operations and Comprehensive Income.

3. Recent Accounting Pronouncements

Recently Issued

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In July 2015, the FASB issued a one-year deferral of ASU 2014-09 making it effective for annual reporting periods beginning on or after December 15, 2017, while also providing for early adoption not to occur before the original effective date. The Company currently anticipates it will adopt the new standard on a modified retrospective basis with the cumulative effect of the change reflected in retained earnings as of January 1, 2018 and to not restate prior periods. The Company has commenced work to assess the impact of the new revenue standard on its principal revenue streams. The Company has not made a determination on the impact to its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842). ASU 2016-02 amends existing lease 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.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments* (Topic 326) Credit Losses. ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income are to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. ASU 2016-13 is effective as of January 1, 2020. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements or footnote disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other* (Topic 350): Simplifying the Test for Goodwill Impairment. ASU 2017-04 will simplify the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. Current guidance requires that companies compute the implied fair value of goodwill under Step 2 by performing procedures to determine the fair value at the impairment testing date of its assets and liabilities (including unrecognized assets and liabilities) following the procedure that would be required in determining the fair value of assets acquired and liabilities assumed in a business combination. This standard will require companies to perform annual or interim goodwill impairment tests by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This standard will be effective for annual periods beginning after December 15, 2019, including interim periods occurring after that date, and will be applied prospectively. Early adoption of this standard is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements or footnote disclosures.

Recently Adopted

In March 2016, the FASB issued ASU No. 2016-09, *Compensation* (Topic 718) Stock Compensation. ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 is effective as of January 1, 2017. Since January 1, 2017, the Company has recognized excess tax benefits and tax deficiencies related to share-based payments in the Condensed Consolidated Statements of Operations and Comprehensive Income as a component of the provision for income taxes on a prospective basis. Such excess tax benefits and tax deficiencies were previously recorded in equity. The Company also began presenting tax-related cash flows resulting from share-based payments as operating activities in the Condensed Consolidated Statements of Cash Flows, and retrospectively revised prior periods to reflect this provision. Accordingly, the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2016 was revised by increasing net cash provided by operating activities by \$0.4 million and by decreasing net cash used in financing activities by \$0.4 million. Lastly, as of January 1, 2017, the Company elected to recognize forfeitures as they occur rather than estimate forfeitures each period on a modified retrospective basis. See Notes 6 and 14 for additional information regarding the impacts on the condensed consolidated financial statements.

4. Investments

All of the Company's investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income, net of related income taxes. The Company held bank certificates of deposit of \$25.8 million and \$20.5 million at September 30, 2017 and December 31, 2016, respectively. There were no unrealized gains or losses on the Company's available-for-sale securities at September 30, 2017 or December 31, 2016.

5. Fair Value Measurements

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants based on assumptions that market participants would use in pricing an asset or liability. As a basis for classifying the fair value measurements, a three-tier fair value hierarchy, which classifies the fair value measurements based on the inputs used in measuring fair value, was established as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets or liabilities; (Level 2) significant other observable inputs that are observable either directly or indirectly; and (Level 3) significant unobservable inputs for which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, the Company records its investments at fair value.

The Company's investments are all classified within Level 2 of the fair value hierarchy. These investments classified within Level 2 of the fair value hierarchy are valued based on matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk.

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

	September 30, 2017	Fair Value Measurements at Reporting Date Using		
		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	\$ 5,324	\$ -	\$ 5,324	\$ -
Investments:				
Bank certificates of deposit	\$ 25,750	\$ -	\$ 25,750	\$ -

	December 31, 2016	Fair Value Measurements at Reporting Date Using		
		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	\$ 68,352	\$ -	\$ 68,352	\$ -
Bank certificates of deposit	750	-	750	-
Total cash equivalents	\$ 69,102	\$ -	\$ 69,102	\$ -
Investments:				
Bank certificates of deposit	\$ 20,500	\$ -	\$ 20,500	\$ -

6. Equity Incentive Plan

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

The Company estimates the fair value of stock options and stock appreciation rights (“SARs”) using the Black-Scholes valuation model. Fair value of restricted stock awards (“RSAs”) and restricted stock units (“RSUs”) are measured by the grant-date price of the Company’s shares. The fair value of each stock option award during the nine-month periods ended September 30, 2017 and 2016, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,			
	2017		2016	
Risk-free interest rate	1.60%	- 1.78%	0.94%	- 1.40%
Expected volatility	41.36%	- 44.30%	48.84%	- 51.61%
Expected life (years)	4.0		4.5	
Expected dividend yield	0.00%		0.00%	

The Company recorded \$1.5 million and \$0.8 million of share-based compensation expense for the three-month periods ended September 30, 2017 and 2016, respectively, for equity compensation awards. The Company recorded \$3.9 million and \$2.3 million of share-based compensation expense for the nine-month periods ended September 30, 2017 and 2016, respectively, for equity compensation awards. The Company presents the expenses related to share-based compensation awards in the same expense line items as cash compensation paid to each of its employees as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of product revenue	\$ 107	\$ 40	\$ 306	\$ 66
Research and development	177	156	340	300
Selling, general and administrative	1,190	601	3,294	1,910
Total stock-based compensation expense	\$ 1,474	\$ 797	\$ 3,940	\$ 2,276

On June 13, 2017, the Company's shareholders approved the Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (the "2017 Plan"). The 2017 Plan replaced the Anika Therapeutics, Inc. Second Amended and Restated 2003 Stock Option and Incentive Plan, as amended, (the "2003 Plan"), as the plan under which future grants to employees, directors, officers, and consultants will be made. The 2017 Plan was originally approved by the Company's Board of Directors on March 31, 2017. The terms of the 2017 Plan provide for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and performance awards that may be settled in cash, stock, or other property. Subject to adjustment for specified types of changes in our capitalization, no more than 1.2 million shares of common stock may be issued under the 2017 Plan.

During the three-month period ended September 30, 2017, a total of 60,609 stock options and 14,506 RSAs were granted under the 2017 Plan. During the nine-month period ended September 30, 2017, a total of 63,109 stock options and 14,506 RSAs were granted under the 2017 Plan and a total of 407,635 stock options were granted under the 2003 Plan. The stock options granted to employees become exercisable or vest ratably over a three-year period. In addition, the Company executed its annual grant of 9,970 RSUs to non-employee directors, and these RSUs vest over a one-year period.

A portion of the stock options granted during the nine-month period ended September 30, 2017 contained certain performance criteria in addition to time-based vesting conditions. For performance-based awards with financial achievement targets, the Company recognizes expense using the graded vesting methodology based on the number of shares expected to vest. Compensation cost associated with performance grants is estimated using the Black-Scholes valuation method multiplied by the expected number of shares to be issued, which is adjusted based on the estimated probabilities of achieving the performance goals. Changes to the probability assessment and the estimated shares expected to vest will result in adjustments to the related share-based compensation expense that will be recorded in the period of the change. If the performance targets are not achieved, no compensation cost is recognized and any previously recognized compensation cost is reversed.

In connection with the adoption of ASU 2016-09, as of January 1, 2017, the Company elected to recognize forfeitures as they occur rather than estimate forfeitures each period, which was applied on a modified retrospective basis. Accordingly, the Company recognized a cumulative adjustment to retained earnings at the beginning of the nine-month period ended September 30, 2017, resulting in a reduction of \$0.5 million.

7. Earnings Per Share (“EPS”)

Basic EPS is calculated by dividing net income by the weighted average number of shares outstanding during the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic earnings per share. Diluted EPS is calculated by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, SARs, RSAs, and RSUs using the treasury stock method.

The following table provides share information used in the calculation of the Company's basic and diluted earnings per share (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Shares used in the calculation of basic earnings per share	14,579	14,625	14,572	14,726
Effect of dilutive securities:				
Stock options, SARs, and RSAs	536	452	493	437
Diluted shares used in the calculation of earnings per share	15,115	15,077	15,065	15,163

Equity awards of 0.5 and 0.6 million shares were outstanding for the three- and nine-month periods ended September 30, 2017, respectively, and were not included in the computation of diluted EPS because the awards' impact on EPS would have been anti-dilutive. Equity awards of 0.3 and 0.4 million shares were outstanding for the three- and nine-month periods ended September 30, 2016, respectively, and were not included in the computation of diluted EPS because the awards' impact on EPS would have been anti-dilutive.

On February 26, 2016, the Company entered into an accelerated stock repurchase agreement with Morgan Stanley & Co. LLC ("Morgan Stanley") pursuant to a Fixed Dollar Accelerated Share Repurchase Transaction ("ASR Agreement") to purchase \$25.0 million of shares of its common stock. Pursuant to the terms of the ASR Agreement, the Company paid Morgan Stanley \$25.0 million in cash and received delivery of 0.4 million shares of the Company's common stock on February 29, 2016 based on a closing market price of \$46.40 per share and the applicable contractual discount.

On August 26, 2016, the Company settled the approximately \$7.5 million remaining under the ASR Agreement, which was recorded as an equity forward sale contract and was included in additional paid-in capital in stockholders' equity in the condensed consolidated balance sheets as it met the criteria for equity accounting. Pursuant to the terms of the ASR Agreement, the final number of shares and the average purchase price was determined at the end of the applicable purchase period, which was August 26, 2016. Based on the volume-weighted average price since the effective date of the ASR Agreement less the applicable contractual discount, Morgan Stanley delivered 0.1 million additional shares to the Company on August 31, 2016. In total, 0.5 million shares were repurchased under the ASR Agreement at an average repurchase price of \$47.08 per share. These shares are held by the Company as authorized but unissued shares pursuant to Massachusetts law. The initial and final delivery of shares resulted in immediate reductions of the outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted net income per share.

8. Inventories

Inventories consist of the following:

	September 30, 2017	December 31, 2016
Raw materials	\$ 7,867	\$ 5,884
Work-in-process	6,564	5,559
Finished goods	5,821	4,540
Total	\$ 20,252	\$ 15,983

9. Intangible Assets

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

Intangible assets as of September 30, 2017 and December 31, 2016 consist of the following:

			September 30, 2017		December 31, 2016	
	Gross Value	Useful Life	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value
Developed technology	\$ 17,100	15	\$(2,644)	\$(7,487)	\$ 6,969	\$ 6,842
In-process research & development	4,406	Indefinite	(1,061)	-	3,345	2,973
Distributor relationships	4,700	5	(415)	(4,285)	-	-
Patents	1,000	16	(158)	(418)	424	412
Eleveess trade name	1,000	9	-	(1,000)	-	-
Total	\$ 28,206		\$(4,278)	\$(13,190)	\$ 10,738	\$ 10,227

The aggregate amortization expense related to intangible assets was \$0.2 million and \$0.3 million for the three-month periods ended September 30, 2017 and 2016, respectively. The aggregate amortization expense related to intangible assets was \$0.7 million and \$0.8 million for the nine-month periods ended September 30, 2017 and 2016, respectively.

10. Goodwill

Through September 30, 2017, there have not been any events or changes in circumstances that indicate that the carrying value of goodwill may not be recoverable. Changes in the carrying value of goodwill were as follows:

	Nine Months Ended September 30, 2017	Twelve Months Ended December 31, 2016
Balance, beginning	\$ 7,214	\$ 7,482
Effect of foreign currency adjustments	890	(268)
Balance, ending	\$ 8,104	\$ 7,214

11. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2017	December 31, 2016
Compensation and related expenses	\$ 2,985	\$ 3,089
Facility construction costs	-	804
Research grants	413	463
Professional fees	897	802
Clinical trial costs	2,136	227
Deferred rent	-	231
Other	85	880
Total	\$ 6,516	\$ 6,496

12. Commitments and Contingencies

In certain of its contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the specific product. The Company may also warrant that the products it manufactures do not infringe, violate, or breach any U.S. or international patent or intellectual property right, trade secret, or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligent acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure to these risks. Based on the Company's historical activity, in combination with its liability insurance coverage, the Company believes the estimated fair value of these indemnification agreements is immaterial. The Company had no accrued warranties at

September 30, 2017 or December 31, 2016 and has no history of claims paid.

The Company is also involved in various legal proceedings arising in the ordinary course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, the Company does not expect the resolution of these legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flow.

13. Leases

On October 9, 2015, our Italian subsidiary, Anika Therapeutics S.r.l. (“Anika S.r.l.”) entered into a build-to-suit lease agreement with Consorzio Zona Industriale E Porto Fluviale di Padova (“ZIP”), as landlord, pursuant to which Anika S.r.l. leases a new European headquarters facility, consisting of approximately 33,000 square feet of general office, research and development, training, and warehousing space located in Padova, Italy. The lease has an initial term of fifteen years, which commenced on March 1, 2017. The lease will automatically renew for up to three additional six-year terms, subject to certain terms and conditions. The Company has the ability to withdraw from this lease subject to certain financial penalties after six years and with no penalties after the ninth year. Beginning on the commencement date, the lease provides for an initial yearly rent of approximately \$0.3 million.

Construction of the new facility commenced during the first quarter of 2016. During the period of construction, the Company was the deemed owner of the facility. Accordingly, the landlord's costs of constructing the facility were capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in the Company's consolidated balance sheet. When the construction concluded on March 1, 2017, the Company removed the construction-in-process asset of \$3.1 million and related liability from its condensed consolidated balance sheet. The Company commissioned ZIP for additional tenant improvements of \$0.8 million, which are recorded within Other long-term assets on the condensed consolidated balance sheet and which will be amortized over the life of the lease. The lease is accounted for as an operating lease based on the Company's assessment of the applicable accounting principles.

14. Income Taxes

Provisions for income taxes were \$3.6 million and \$12.6 million for the three- and nine-month periods ended September 30, 2017, based on an effective tax rate of 34.6% for both periods. Provisions for income taxes were \$4.8 million and \$13.6 million for the three- and nine-month periods ended September 30, 2016, based on effective tax rates of 35.0% and 35.8%, respectively. The decrease in income taxes for the three- and nine-month periods ended September 30, 2017 resulted from decreased income before income taxes in addition to a net decrease in the effective tax rate as compared to the same period in the prior year. The net decrease in the effective tax rate for the three- and nine-month periods ended September 30, 2017, as compared to the same periods in 2016, was primarily due to the increase in the expected research and development and state investment tax credits. In addition, the Company realized windfall tax benefits related to share-based payments in connection with the adoption of ASU 2016-09 during the period. The amount of excess tax benefits recognized as a discrete period income tax benefit was \$0.0 and \$0.3 million for the three- and nine-month periods ended September 30, 2017, respectively, which decreased the effective tax rate for the interim periods by 0.0% and 0.9%, respectively. Prior to the adoption of ASU 2016-09 excess tax benefits and deficiencies were recorded in equity. The amount of excess tax benefits recognized through additional paid-in-capital was \$0.0 million and \$0.4 million for the three- and nine-month periods ended September 30, 2016, respectively.

The Company files income tax returns in the United States on a federal basis, in certain U.S. states, and in Italy. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate.

In connection with the preparation of the financial statements, the Company performed an analysis to ascertain if it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its net operating loss carry-forward. The Company has concluded that the positive evidence outweighs the negative evidence and, thus, that the deferred tax assets not otherwise subject to a valuation allowance are realizable on a “more likely than not” basis. As such, the Company did not record a valuation allowance at September 30, 2017 or December 31, 2016.

15. DePuy Synthes Mitek Sports Medicine Agreements

In December 2011, the Company entered into a fifteen-year licensing agreement with DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics, Inc. (“Mitek”), to exclusively market MONOVISC in the U.S. The Company fully recognized revenue for a milestone payment of \$5.0 million as a result of MONOVISC achieving \$100.0 million in U.S. end-user sales within a consecutive 12-month period ending in June 2017.

ORTHOVISC became available for sale in the United States on March 1, 2004, and it is marketed exclusively by Mitek under the terms of an initial ten-year licensing, distribution, supply, and marketing agreement entered into in December 2003. The agreement was extended by Mitek for additional five-year terms in 2012 and in 2017, with the

current agreement to expire on December 20, 2023.

16. Segment and Geographic Information

The Company has one reportable operating segment for the purposes of assessing performance and determining the allocation of resources.

Product revenue by product group is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Orthobiologics	\$ 23,990	\$ 22,428	\$ 68,686	\$ 65,319
Surgical	1,765	1,173	4,395	3,924
Dermal	358	594	1,235	1,558
Other	1,065	1,588	4,583	3,835
Product Revenue	\$ 27,178	\$ 25,783	\$ 78,899	\$ 74,636

Total revenue by geographic location and as a percentage of overall total revenue for the three- and nine-month periods ended September 30, 2017 and 2016 are as follows:

Geographic Location:	Three Months Ended September 30, 2017			2016		
	Total Revenue	Percentage of Revenue	%	Total Revenue	Percentage of Revenue	%
United States	\$22,227	82	%	\$21,126	82	%
Europe	2,832	10	%	2,703	10	%
Other	2,125	8	%	1,960	8	%
Total Revenue	\$27,184	100	%	\$25,789	100	%

Geographic Location:	Nine Months Ended September 30, 2017			2016		
	Total Revenue	Percentage of Revenue	%	Total Revenue	Percentage of Revenue	%
United States	\$68,624	82	%	\$61,032	82	%
Europe	9,743	11	%	8,240	11	%
Other	5,665	7	%	5,381	7	%
Total Revenue	\$84,032	100	%	\$74,653	100	%

17. Subsequent Event

On October 24, 2017, the Company, as borrower, entered into a new five-year agreement with Bank of America, N.A., as administrative agent, swingline lender and issuer of letters of credit, for a \$50.0 million senior revolving line of credit (the "Credit Agreement"). Subject to certain conditions, the Company may request up to an additional \$50.0 million in commitments for a maximum aggregate commitment of \$100.0 million, which requests must be approved by the Revolving Lenders (as defined in the Credit Agreement). Loans under the Credit Agreement generally bear interest equal to, at the Company's option, either: (i) LIBOR plus the Applicable Margin, as defined below, or the (ii) Base Rate, defined as the highest of: (a) the Federal Funds Rate plus 0.50%, (b) Bank of America, N.A.'s prime rate and (c) the one month LIBOR adjusted daily plus 1.0%, plus the Applicable Margin. The Applicable Margin ranges from 0.25% to 1.75% based on the Company's consolidated leverage ratios at the time of the borrowings under the Credit Agreement. The Company has agreed to pay a commitment fee in an amount that is equal to 0.25% per annum on the actual daily unused amount of the credit facility and that is due and payable quarterly in arrears. Loan origination costs will be amortized over the five-year term of the Credit Agreement.

The Credit Agreement contains customary representations, warranties, affirmative and negative covenants, including financial covenants, events of default and indemnification provisions in favor of the Lenders (as defined in the Credit

Agreement). The covenants include restrictions governing the Company's leverage ratio and interest coverage ratio, its incurrence of liens and indebtedness, and its entry into certain merger and acquisition transactions or dispositions and other matters, all subject to certain exceptions. The financial covenants require us not to exceed certain maximum leverage and interest coverage ratios. The Lenders have been granted a first priority lien and security interest in substantially all of the Company's assets, except for certain intangible assets.

ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS 2. OF OPERATIONS

You should read the following discussion in conjunction with our financial statements and related notes appearing elsewhere in this report. In addition to historical information, this report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 concerning our business, consolidated financial condition, and results of operations. The Securities and Exchange Commission ("SEC") encourages companies to disclose forward-looking statements so that investors can better understand a company's future prospects and make informed investment decisions. Forward-looking statements are subject to risks and uncertainties, many of which are outside our control, which could cause actual results to differ materially from these statements. Therefore, you should not rely on any of these forward-looking statements. Forward-looking statements can be identified by such words as "will," "likely," "may," "believe," "expect," "anticipate," "intend," "seek," "designed," "develop," "would," "future," "can," "could," and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, operations, costs, plans, and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements regarding expected future operating results, expectations regarding the timing and receipt of regulatory results, anticipated levels of capital expenditures, and expectations of the effect on our financial condition of claims, litigation, and governmental and regulatory proceedings.

Please also refer to those factors described in Part II, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2016 for important factors that we believe could cause actual results to differ materially from those in our forward-looking statements. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments, or otherwise.

Management Overview

We are a global, integrated orthopedic 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 cartilage repair. We have over two decades of global expertise developing, manufacturing, and commercializing our products based on our proprietary hyaluronic acid ("HA") technology. Our 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.

Our therapeutic offerings consist of products in the following areas: Orthobiologics, Dermal, Surgical, and Other, which includes our ophthalmic and veterinary products. All of our products are based on HA, a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA

plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

Our proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to therapeutic use. Our patented technology chemically modifies HA to allow for longer residence time in the body. We also offer products made from HA based on two other technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Our technologies are protected by an extensive portfolio of owned and licensed patents.

Since our inception in 1992, we have utilized a commercial partnership model for the distribution of our products to end-users. Our strong, worldwide network of distributors has historically provided, and continues to provide, a solid foundation for our revenue growth and territorial expansion. In 2015, we made the strategic decision to commercialize our next generation viscosupplementation product, CINGAL, in the United States ourselves, initially through the engagement of a contract sales organization. Ultimately, we intend to transition the direct sales function into our company as part of a broader buildout of our commercial capabilities. We believe that the combination of the direct and distribution commercial models will maximize the revenue potential from our current and future product portfolio.

We began a strategic project in 2015 to move the manufacturing of our HYAFF-based products, which were previously manufactured under an existing contract manufacturing agreement with a third party in Italy, to our Bedford, Massachusetts facility. Our main purposes behind this strategic move are to enhance our research and development capabilities with the aim of accelerating future product development and to improve the efficiency of our manufacturing process. We expect to expend approximately \$25.0 million on this project. Since project inception through September 30, 2017, we have expended approximately \$22.7 million on the project, and we have completed key planned project milestones to date. We expect the HYAFF manufacturing to be fully operational before the end of 2017.

Please see the section captioned “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations-Management Overview” in our Annual Report on Form 10-K for the year ended December 31, 2016, for a description of each of the above therapeutic areas, including the individual products.

Research and Development

Our research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities for our existing and new products. Our development focus includes products for tissue protection, repair, and regeneration. We anticipate that we will continue to commit significant resources to research and development, including clinical trials in the future.

Our second single-injection osteoarthritis product under development in the United States is CINGAL, which is composed of our proprietary cross-linked HA material combined with an approved steroid and is designed to provide both short- and long-term pain relief to patients. We completed an initial CINGAL phase III clinical trial, including the associated statistical analysis for 368 enrolled patients, during the fourth quarter of 2014 with data indicating that the product met all primary and secondary endpoints relative to placebo set forth for the trial. During the first half of 2015, we completed a CINGAL retreatment study with 242 patients who had participated in the phase III clinical trial and reported safety data related to the retreatment study. This initial phase III clinical trial and the associated retreatment study supported the Health Canada and CE Mark approval of the product, and the commercial launch of the product in both Canada and the European Union occurred in the second quarter of 2016. In the United States, after discussions with the U.S. Food and Drug Administration (“FDA”) related to the regulatory pathway for CINGAL, we conducted a formal meeting with the FDA’s Office of Combination Products (“OCP”) to present and discuss our data in September 2015, and we submitted a formal request for designation with OCP a month later. In its response to our formal request for designation, OCP assigned the product to the FDA’s Center for Drug Evaluation and Research (“CDER”) as the lead agency center for premarket review and regulation. Since then, we have been in ongoing discussions with CDER to understand the requirements for submitting a New Drug Application (“NDA”) for CINGAL. We held a meeting with CDER in September 2016 to align on an approval framework and on submission requirements for this NDA for CINGAL, including the execution of an additional Phase III clinical trial to supplement our existing CINGAL pivotal study data. We submitted an Investigational New Drug Application (“IND”) in late 2016, and discussions with CDER indicated no objections to our clinical protocol design. As a result, we commenced work on this second Phase III clinical trial in the first quarter of 2017, and the first patient was treated in the second quarter of 2017. Enrollment in this second Phase III clinical trial was completed during October 2017. We have also initiated a nine-month extended follow-up study in conjunction with the second Phase III clinical trial to investigate the efficacy of CINGAL over this longer period. This extended follow-up study will not impact the timeline for submission of the NDA for CINGAL following the completion of the second Phase III clinical trial.

We have several research and development programs underway for new products, including for HYALOFAST (in the United States), an innovative product for cartilage tissue repair and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is commercially

available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption (“IDE”) for HYALOFAST to the FDA, which was approved in July 2015. We commenced patient enrollment in a clinical trial in December 2015, and we are advancing site initiations and patient enrollment activities. In the second quarter of 2016, a supplement to the HYALOFAST IDE was approved to expand the inclusion criteria for the clinical study. The purpose of this supplement is to allow us to increase enrollment rates with the ultimate goal of decreasing the time needed to complete the clinical trial. In addition, we are currently proceeding with other research and development programs, one of which utilizes our proprietary HA technology to treat pain associated with common repetitive overuse injuries, such as lateral epicondylitis, also known as tennis elbow. We submitted a CE Mark application for this treatment during the first quarter of 2016 and received a CE Mark for the treatment of pain associated with tennis elbow in December 2016. Outside of the United States, this product will be marketed under the trade name ORTHOVISC-T. In the second quarter of 2016, we submitted an IDE to the FDA to conduct a phase III clinical trial for this treatment, which was approved by the FDA in June 2016. We also have other research and development programs underway focused on expanding the indications of our current products, including one program being conducted and funded by our U.S. MONOVISC distribution partner, DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics, Inc. (“Mitek”), seeking to expand MONOVISC’s indication to include the treatment of pain associated with osteoarthritis of the hip. In third quarter of 2017, we also submitted an application to the FDA for 510(k) clearance of an injectable HA-based bone repair treatment, which derived from previous research and development activities related to HYALOBONE.

In June 2015, we entered into an agreement with the Institute for Applied Life Sciences at the University of Massachusetts Amherst to collaborate on research to develop a therapy for rheumatoid arthritis. The purpose of this research is to develop a novel modality for the treatment of rheumatoid arthritis and, if successful, it is expected to yield a potential product candidate that we could begin to move towards commercialization through additional pre-clinical studies.

Results of Operations

Three- and Nine-Months Ended September 30, 2017 Compared to Three- and Nine-Months Ended September 30, 2016

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017	2016	\$	%	2017	2016	\$	%
	Inc/(Dec)				Inc/(Dec)			
	(in thousands, except percentages)				(in thousands, except percentages)			
Product revenue	\$27,178	\$25,783	\$1,395	5 %	\$78,899	\$74,636	\$4,263	6 %
Licensing, milestone and contract revenue	6	6	-	0 %	5,133	17	5,116	*
Total revenue	27,184	25,789	1,395	5 %	84,032	74,653	9,379	13 %
Operating expenses:								
Cost of product revenue	6,250	4,998	1,252	25 %	18,648	16,488	2,160	13 %
Research and development	5,842	2,822	3,020	107 %	14,521	7,773	6,748	87 %
Selling, general and administrative	4,823	4,280	543	13 %	14,862	12,525	2,337	19 %
Total operating expenses	16,915	12,100	4,815	40 %	48,031	36,786	11,245	31 %
Income from operations	10,269	13,689	(3,420)	(25 %)	36,001	37,867	(1,866)	(5 %)
Interest income, net	261	93	168	181 %	335	214	121	57 %
Income before income taxes	10,530	13,782	(3,252)	(24 %)	36,336	38,081	(1,745)	(5 %)
Provision for income taxes	3,643	4,830	(1,187)	(25 %)	12,587	13,619	(1,032)	(8 %)
Net income	\$6,887	\$8,952	\$(2,065)	(23 %)	\$23,749	\$24,462	\$(713)	(3 %)
Product gross profit	\$20,928	\$20,785	\$143	1 %	\$60,251	\$58,148	\$2,103	4 %
Product gross margin	77 %	81 %			76 %	78 %		

* Percentage increase has been omitted due to magnitude.

Product Revenue

Product revenue for the three-month period ended September 30, 2017 was \$27.2 million, an increase of 5% as compared to \$25.8 million for the three-month period ended September 30, 2016. Product revenue for the nine-month period ended September 30, 2017 was \$78.9 million, an increase of 6% as compared to \$74.6 million for the nine-month period ended September 30, 2016. For the three-month period ended September 30, 2017, the increase in product revenue was mainly driven by the growth of our orthobiologics and surgical franchises. For the nine-month period ended September 30, 2017, the increase in product revenue was mainly driven by the growth of our orthobiologics and surgical franchises and the growth of our veterinary product in the other franchise category, with such increase being partially offset by a decrease in revenue from our dermal franchise.

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

The following tables present product revenue by product group for the three- and nine-month periods ended September 30, 2017 and 2016:

Three Months Ended September 30,					
	2017	2016	\$ Inc/(Dec)	% Inc/(Dec)	
(in thousands, except percentages)					
Orthobiologics	\$23,990	\$22,428	\$ 1,562	7	%
Surgical	1,765	1,173	592	50	%
Dermal	358	594	(236)	(40	%)
Other	1,065	1,588	(523)	(33	%)
Total	\$27,178	\$25,783	\$ 1,395	5	%

Nine Months Ended September 30,					
	2017	2016	\$ Inc/(Dec)	% Inc/(Dec)	
(in thousands, except percentages)					
Orthobiologics	\$68,686	\$65,319	\$ 3,367	5	%
Surgical	4,395	3,924	471	12	%
Dermal	1,235	1,558	(323)	(21	%)
Other	4,583	3,835	748	20	%
Total	\$78,899	\$74,636	\$ 4,263	6	%

Orthobiologics

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 7% and 5% for the three- and nine-month periods ended September 30, 2017, respectively, as compared to the same periods in 2016. The growth in the three- and nine-month periods ended September 30, 2017 was primarily due to an increase in worldwide MONOVISC revenue. MONOVISC worldwide revenue increased during the three- and nine-month periods ended September 30, 2017 as a result of robust and growing end-user demand for the product. MONOVISC's strong growth is further augmented as end-user demand in the market for viscosupplementation products more generally continues to shift from multi-injection products, including ORTHOVISC, to single-injection products, such as MONOVISC, both domestically and internationally. CINGAL and ORTHOVISC-T, both of which launched internationally during the second half of 2016, also contributed to the growth of orthobiologics revenue during the period. We expect orthobiologics revenue to continue to grow for the remainder of 2017, led by increased MONOVISC revenue in domestic and international markets, including in India, Australia, New Zealand, and Taiwan, where regulatory approvals were achieved in the second quarter and third quarters of 2017, the commercial availability of CINGAL in Canada and Europe, as well as overall revenue growth from our viscosupplementation products both domestically and internationally.

Surgical

Our surgical franchise consists of products used to prevent surgical adhesions and to treat ear, nose, and throat ("ENT") disorders. Sales of our surgical products increased 50% and 12% for the three- and nine-month periods ended September 30, 2017 to \$1.8 million and \$4.4 million, respectively, as compared to the same periods in 2016. The increase in surgical product revenue for the three- and nine-month periods was primarily due to an increase in sales to our worldwide ENT commercial partner. We expect surgical product revenue to increase modestly in 2017, as compared to 2016, primarily due to increased worldwide sales of our ENT products.

Dermal

Our dermal franchise consists of advanced wound care products, which are based on our HYAFF technology, and aesthetic dermal fillers. Our advanced wound care products treat complex skin wounds ranging from burns to diabetic ulcers, with HYALOMATRIX and HYALOFILL as the lead products. For the three- and nine-month periods ended September 30, 2017, dermal product sales decreased 40% and 21%, respectively, as compared to the same periods in 2016. This year-to-date decrease reflects order timing by our distribution partners. We expect dermal revenue to increase in 2017 as compared to 2016 primarily due to increased end-user demand and geographic expansion related to our advanced wound care products in the U.S. and European markets.

Other

Other product revenue includes revenues from our ophthalmic and veterinary franchises. Product revenue from these franchises decreased for the three-month and increased for the nine-month periods ended September 30, 2017 as compared to the same periods in 2016. We expect other revenue to increase in 2017 as compared to 2016, driven primarily by our veterinary product.

Licensing, milestone and contract revenue

Licensing, milestone and contract revenue for the three- and nine-month periods ended September 30, 2017 was \$6 thousand and \$5.1 million, as compared to \$6 thousand and \$17 thousand for the same periods in 2016. Revenue for the nine-month period ended September 30, 2017 included a \$5.0 million milestone payment associated with our U.S. license agreement with Mitek for MONOVISC that was received and fully recognized as a result of U.S. MONOVISC 12-month end-user sales exceeding \$100.0 million.

Product gross profit and margin

Product gross profit for the three- and nine-month periods ended September 30, 2017 increased \$143 thousand and \$2.1 million to \$20.9 and \$60.3 million, respectively, representing 77% and 76% of product revenue. Product gross profit for the three- and nine- months ended September 30, 2016 was \$20.8 million and \$58.1 million, representing 81% and 78% of product revenue. The decrease in product gross margin for the three and nine-month periods ended September 30, 2017, as compared to the same periods in 2016, was primarily attributable to higher production volume in the prior year periods and inventory write-offs in 2017. This current product gross margin may not be indicative of the rest of the year due to dynamics such as future revenue mix and production volume variability.

Research and development

Research and development expenses for the three- and nine-month periods ended September 30, 2017 were \$5.8 million and \$14.5 million, representing 21.5% and 17.3% of total revenue for the respective periods, an increase of \$3.0 million and \$6.7 million, respectively, as compared to the same periods in 2016. The increase in research and development expenses was primarily due to a higher level of clinical and regulatory activities, including our HYALOFAST and CINGAL phase III clinical studies. Furthermore, we also increased our pre-clinical product development activities with respect to certain product candidates in our research and development pipeline. Research and development spending is expected to increase in 2017 and thereafter, as compared to 2016, as we further develop new products and line extensions and initiate new clinical trials based on our existing technology assets, including CINGAL and HYALOFAST, as well as increase development activities for other products and line extensions in the pipeline.

Selling, general and administrative

Selling, general and administrative (“SG&A”) expenses for the three- and nine-month periods ended September 30, 2017 were \$4.8 million and \$14.9 million, or 17.7% of total revenue for both periods, an increase of \$0.5 million and \$2.3 million, respectively, as compared to the same periods in 2016. SG&A expenses increased for the three- and nine-month periods ended September 30, 2017 primarily as a result of increases in personnel related costs, external professional fees, and marketing initiatives to support the CINGAL and ORTHOVISC-T international launches. We expect SG&A expenses for 2017 will increase to reflect the support, including the implementation of improved operational and financial technology platforms, required to grow our business both domestically and internationally.

Income taxes

Provisions for income taxes were \$3.6 million and \$12.6 million for the three- and nine-month periods ended September 30, 2017, based on an effective tax rate of 34.6% for both periods. Provisions for income taxes were \$4.8 million and \$13.6 million for the three- and nine-month periods ended September 30, 2016, based on effective tax rates of 35.0% and 35.8%, respectively. The decrease in income taxes for the three- and nine-month periods ended September 30, 2017 resulted from decreased income before income taxes and a net decrease in the effective tax rate as compared to the same periods in the prior year. The net decrease in the effective tax rate for the three- and nine-month periods ended September 30, 2017, as compared to the same periods in 2016, was primarily due to the increase in the expected research and development and state investment tax credits.

In addition, we realized windfall tax benefits related to share-based payments in connection with the adoption of ASU 2016-09 as of January 1, 2017. The amount of excess tax benefits recognized as a discrete period income tax benefit was \$0.0 and \$0.3 million for the three- and nine-month periods ended September 30, 2017, respectively, which

decreased the effective tax rate for the interim periods by 0.0% and 0.9%, respectively. Prior to the adoption of ASU 2016-09 excess tax benefits and deficiencies were recorded in equity. The amount of excess tax benefits recognized through additional paid-in-capital was \$0.0 million and \$0.4 million for the three- and nine-month periods ended September 30, 2016, respectively.

Liquidity and Capital Resources

On October 24, 2017, we entered into a five-year agreement for a \$50.0 million senior revolving line of credit, and as of October 24, 2017, \$50.0 million was available for borrowing under the line of credit. See Note 17 to the condensed consolidated financial statements for additional information regarding the line of credit.

We expect that our requirements for cash to fund operations and capital expenditures will increase as the scope of our operations expands. Historically, we have generated positive cash flow from operations, which together with our available cash and investments have met our cash requirements. Cash, cash equivalents, and investments totaled approximately \$152.7 million and \$124.8 million at September 30, 2017 and December 31, 2016, respectively. Working capital totaled approximately \$187.3 million at September 30, 2017 and \$161.6 million at December 31, 2016. We believe that we have adequate financial resources, including amounts available under the line of credit, to support our business for at least the next twelve months beyond the release of the financial statements.

Cash provided by operating activities was \$33.8 million for the nine-month period ended September 30, 2017, as compared to cash provided by operating activities of \$18.4 million for the same period in 2016. This increase in cash was primarily related to a decrease in accounts receivable, an increase in accounts payable, and an increase in income taxes payable, due to the timing of payments, offset, in part, by an increase in inventories.

Cash used in investing activities was \$11.8 million for the nine-month period ended September 30, 2017, as compared to cash used in investing activities of \$7.1 million for the same period in 2016. The increase in cash used in investing activities was primarily the result of the purchase of investments offset by maturities of investments during the first half of 2017. Furthermore, expenditures for the buildout of our Bedford, Massachusetts facility are declining and we expect to complete validation by the end of 2017.

Cash provided by financing activities was \$0.3 million for the nine-month period ended September 30, 2017, as compared to cash used by financing activities totaling \$24.0 million for the same period in 2016. The decrease in cash used in financing activities for the nine-month period ended September 30, 2017 was primarily attributable to the Fixed Dollar Accelerated Share Repurchase Transaction to repurchase \$25.0 million of shares of our common stock in February 2016.

Critical Accounting Estimates

There were no other significant changes in our critical accounting estimates during the nine months ended September 30, 2017 to augment the critical accounting estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

Recent Accounting Pronouncements

A discussion of Recent Accounting Pronouncements is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and is updated in Note 3 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Contractual Obligations and Other Commercial Commitments

Our contractual obligations and other commercial commitments are summarized in the section captioned "Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Contractual Obligations and Other Commercial Commitments" in our Annual Report on Form 10-K for the year ended December 31, 2016. We had no material changes outside the ordinary course of business to our contractual obligations reported in our 2016 Annual Report on Form 10-K during the first nine months of 2017.

To the extent that funds generated from our operations, together with our existing capital resources, are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, including through the previously discussed \$50.0 million senior revolving line of credit, strategic alliances with corporate partners and others, or through other sources. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

Off-balance Sheet Arrangements

We do not use special purpose entities or other off-balance sheet financing techniques, except for operating leases, that we believe have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, and the ways we manage them, are summarized in the section captioned “Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2016. There have been no material changes in the first nine months of 2017 to our market risks or to our management of such risks.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in SEC rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by our company in the reports it files or submits under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the three-month period ended September 30, 2017 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are involved in various legal proceedings arising in the ordinary course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, we do not expect the resolution of these legal proceedings to have a material adverse effect on our financial position, results of operations, or cash flow. There have been no material changes to the information provided in the section captioned “Part I, Item 3, Legal Proceedings” in our Annual Report on Form 10-K for the year ended December 31, 2016.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors described in the section captioned “Part I, Item 1A, Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned “Part I, Item 1A, Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, which could materially affect our business, financial condition, or future results. The risks described in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition, and/or operating results.

ITEM 6. EXHIBITS

Exhibit No. Description

- (10)
- *10.1 Credit Agreement, dated as of October 24, 2017, among Anika Therapeutics, Inc., certain subsidiaries of Anika Therapeutics, Inc. as are or may from time to time become parties to the Credit Agreement, Bank of America, N.A., as administrative agent, swingline lender and issuer of letters of credit, and the lenders party thereto.
- *10.2 Security and Pledge Agreement, dated as of October 24, 2017, among Anika Therapeutics, Inc., certain subsidiaries of Anika Therapeutics, Inc. listed on the signature pages thereto, and Bank of America, N.A., as administrative agent.
- 10.3 Negotiated Settlement Agreement and General Release, dated July 13, 2017, by and between Stephen Mascioli, M.D., MPH and Anika Therapeutics, Inc., incorporated herein by reference to Exhibit 10.1 to Form 8-K, filed with the SEC on July 14, 2017.
- 10.4 Employment Agreement, dated July 27, 2017, by and between Anika Therapeutics, Inc. and Joseph Darling, incorporated herein by reference to Exhibit 10.1 to Form 8-K, filed with the SEC on July 27, 2017.
- (31) Rule 13a-14(a)/15d-14(a) Certifications.
- *31.1 Certification of Charles H. Sherwood, Ph.D., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- *31.2 Certification of Sylvia Cheung pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (32) Section 1350 Certifications.
- **32.1 Certification of Charles H. Sherwood, Ph.D., and Sylvia Cheung, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (101) XBRL
- *101 The following materials from Anika Therapeutics, Inc.’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the SEC on October 27, 2017, formatted in XBRL (eXtensible Business Reporting Language), as follows:
- i. Condensed Consolidated Balance Sheets as of September 30, 2017 (unaudited) and December 31, 2016 (unaudited)
 - ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2017 and September 30, 2016 (unaudited)
 - iii.

Edgar Filing: Anika Therapeutics, Inc. - Form 10-Q

Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2017 and
September 30, 2016 (unaudited)

iv. Notes to Condensed Consolidated Financial Statements (unaudited)

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

ANIKA THERAPEUTICS, INC.

Date: October 27, 2017 By: /s/ SYLVIA CHEUNG

Sylvia Cheung

Chief Financial Officer

(Authorized Officer and Principal Financial Officer)