

Anika Therapeutics, Inc.  
Form 10-Q  
November 01, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**<sup>x</sup> QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

**For the quarterly period ended September 30, 2016**

**<sup>0</sup> 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)

Registrant's Telephone Number, Including Area Code: **(781) 457-9000**

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report: **N/A**

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Non-accelerated filer ☐

Smaller reporting

Large accelerated filer ☐ Accelerated filer ☒ (Do not check if a smaller  
reporting company)

company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes ☐ No ☒

As of October 26, 2016 there were 14,623,225 outstanding shares of Common Stock, par value \$.01 per share.

**ANIKA THERAPEUTICS, INC.**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>Part I</u>	
<u>Financial Information</u>	
<u>Item 1.</u>	<u>3</u>
<u>Financial Statements (unaudited):</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three and nine months ended September 30, 2016 and 2015</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015</u>	<u>5</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>6</u>
<u>Item 2.</u>	<u>13</u>
<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	
<u>Item 3.</u>	<u>18</u>
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	
<u>Item 4.</u>	<u>18</u>
<u>Controls and Procedures</u>	
<u>Part II</u>	
<u>Other Information</u>	
<u>Item 1.</u>	<u>18</u>
<u>Legal Proceedings</u>	
<u>Item 1A.</u>	<u>19</u>
<u>Risk Factors</u>	
<u>Item 2.</u>	<u>19</u>
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
<u>Item 3.</u>	<u>19</u>
<u>Defaults Upon Senior Securities</u>	
<u>Item 4.</u>	<u>19</u>
<u>Mine Safety Disclosures</u>	
<u>Item 5.</u>	<u>19</u>
<u>Other Information</u>	
<u>Item 6.</u>	<u>20</u>
<u>Exhibits</u>	
<u>Signatures</u>	<u>21</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)

<b>ASSETS</b>	September 30, 2016	December 31, 2015
Current assets:		
Cash and cash equivalents	\$98,047	\$110,707
Investments	22,250	27,751
Accounts receivable, net of reserves of \$224 and \$167 at September 30, 2016 and December 31, 2015, respectively	21,833	21,652
Inventories	18,020	14,938
Prepaid expenses and other current assets	924	1,385
Total current assets	161,074	176,433
Property and equipment, net	51,058	40,108
Long-term deposits and other	69	69
Intangible assets, net	11,171	11,656
Goodwill	7,690	7,482
Total Assets	\$231,062	\$235,748
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$1,949	\$8,302
Accrued expenses and other current liabilities	5,423	4,778
Income taxes payable	217	4,198
Total current liabilities	7,589	17,278
Other long-term liabilities	2,556	781
Long-term deferred revenue	59	66
Deferred tax liability	6,315	6,775
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250 shares authorized, no shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	-	-
Common stock, \$.01 par value; 60,000 and 30,000 shares authorized, 14,623 and 15,037 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	146	150

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

Additional paid-in-capital	60,374	81,685
Accumulated other comprehensive loss	(6,101 )	(6,649 )
Retained earnings	160,124	135,662
Total stockholders' equity	214,543	210,848
Total Liabilities and Stockholders' Equity	\$231,062	\$235,748

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,	
	2016	2015	2016	2015
Product revenue	\$25,783	\$23,676	\$74,636	\$62,089
Licensing, milestone and contract revenue	6	5	17	16
Total revenue	25,789	23,681	74,653	62,105
Operating expenses:				
Cost of product revenue	4,998	5,176	16,488	14,764
Research & development	2,822	2,061	7,773	5,971
Selling, general & administrative	4,280	3,309	12,525	10,302
Total operating expenses	12,100	10,546	36,786	31,037
Income from operations	13,689	13,135	37,867	31,068
Interest income, net	93	34	214	82
Income before income taxes	13,782	13,169	38,081	31,150
Provision for income taxes	4,830	4,789	13,619	11,435
Net income	\$8,952	\$8,380	\$24,462	\$19,715
Basic net income per share:				
Net income	\$0.61	\$0.56	\$1.66	\$1.32
Basic weighted average common shares outstanding	14,625	14,967	14,726	14,945
Diluted net income per share:				
Net income	\$0.59	\$0.55	\$1.61	\$1.29
Diluted weighted average common shares outstanding	15,077	15,316	15,163	15,311
Net income	\$8,952	\$8,380	\$24,462	\$19,715
Other comprehensive income (loss):				
Unrealized gain (loss) on securities, net of tax	-	2	-	(1 )
Foreign currency translation adjustment	310	258	548	(1,572 )
Total other comprehensive income (loss)	310	260	548	(1,573 )
Comprehensive income	\$9,262	\$8,640	\$25,010	\$18,142

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	2015
Cash flows from operating activities:		
Net income	\$24,462	\$19,715
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,777	2,800
Stock-based compensation expense	2,276	1,562
Deferred income taxes	(571 )	(16 )
Provision for doubtful accounts	52	-
Provision for inventory	259	149
Tax benefit from equity awards	(421 )	(877 )
Changes in operating assets and liabilities:		
Accounts receivable	(104 )	(6,550 )
Inventories	(3,229 )	82
Prepaid expenses, other current and long-term assets	355	403
Accounts payable	(5,390 )	970
Accrued expenses and other current liabilities	1,091	(120 )
Deferred revenue	(43 )	(9 )
Income taxes payable	(3,496 )	5,757
Other long-term liabilities	(61 )	(76 )
Net cash provided by operating activities	17,957	23,790
Cash flows from investing activities:		
Proceeds from maturity of investments	37,750	14,750
Purchase of investments	(32,250 )	(30,009 )
Purchase of property and equipment	(12,608 )	(2,028 )
Net cash used in investing activities	(7,108 )	(17,287 )
Cash flows from financing activities:		
Repurchases of common stock	(25,000 )	-
Proceeds from exercise of equity awards	988	1,075
Tax benefit from equity awards	421	877
Net cash (used in) provided by financing activities	(23,591 )	1,952
Exchange rate impact on cash	82	(142 )
Increase (decrease) in cash and cash equivalents	(12,660 )	8,313
Cash and cash equivalents at beginning of period	110,707	100,156

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

Cash and cash equivalents at end of period	\$98,047	\$108,469
Supplemental disclosure of cash flow information:		
Non-cash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$474	\$2,197
Build-to-suite 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 shares and per share amounts or as otherwise noted)**

**(unaudited)**

**1. Nature of Business**

Anika Therapeutics, Inc. 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. The year-end consolidated balance sheet is derived from the Company's audited financial statements, but does not include all disclosures required by US GAAP. 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, 2016, the results of its operations for the three- and nine-month periods ended September 30, 2016 and 2015, and cash flows for the nine-month periods ended September 30, 2016 and 2015.

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, 2015. The results of operations for the three- and nine-month periods ended September 30, 2016

are not necessarily indicative of the results to be expected for the year ending December 31, 2016. Certain prior period amounts have been reclassified to conform to the current period presentation. There was no impact on operating 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 deferral of ASU 2014-09 of one year 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 is assessing the appropriate method for implementing ASU 2014-09, as well as the impact the adoption of ASU 2014-09 will have on its consolidated financial statements.

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

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, 2018. Early adoption is permitted. The Company is assessing ASU 2016-09 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 Company is assessing ASU 2016-13, and adoption of this standard is not expected to have a material impact on its consolidated financial statements or footnote disclosures.

#### *Recently Adopted*

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330) Simplifying the Measurement of Inventory. ASU 2015-11 more closely aligns the measurement of inventory in US GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business less reasonably predictable costs of completion, disposal, and transportation. The provisions of ASU 2015-11 are effective for annual and interim periods beginning after December 15, 2016. ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company adopted this standard for the interim reporting period ended March 31, 2016. The adoption of this standard did not have a material impact on the Company's financial position or results of operations.

#### **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 \$22.3 million and \$25.8 million at September 30, 2016 and December 31, 2015, respectively. The Company also held corporate debt securities of \$2.0 million at December 31, 2015. There were no unrealized gains or losses on the Company's available-for-sale securities at September 30, 2016 or December 31, 2015.

## 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:

		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)	
	September 30, 2016							
Cash equivalents:								
Money market funds	\$ 67,299	\$-	\$ 67,299	\$	-			
Investments:								
Bank certificates of deposit	\$ 22,250	\$-	\$ 22,250	\$	-			

		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)	
	December 31, 2015							
Cash equivalents:								
Money market funds	\$ 61,385	\$-	\$ 61,385	\$	-			
Bank certificates of deposit	250	-	250					
Total cash equivalents	\$ 61,635	\$-	\$ 61,635	\$	-			
Investments:								
Corporate debt securities	\$ 2,001	\$-	\$ 2,001	\$	-			
Bank certificates of deposit	25,750	-	25,750					
Total investments	\$ 27,751	\$-	\$ 27,751	\$	-			

## 6. Equity Incentive Plan

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 three- and nine-month periods ended September 30, 2016 and 2015, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,			
	2016		2015	
Risk free interest rate	0.94%	-	1.40%	1.15% - 1.46%
Expected volatility	48.84%	-	51.61%	53.15% - 54.65%
Expected life (years)	4.5		4.5	
Expected dividend yield	0.00%		0.00%	

The Company recorded \$0.8 million and \$0.5 million of share-based compensation expense for the three-month periods ended September 30, 2016 and 2015, respectively, for equity compensation awards. The Company recorded \$2.3 million and \$1.6 million of share-based compensation expense for the nine-month periods ended September 30, 2016 and 2015, respectively, for equity compensation awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the respective recipients.

During the three-month period ended September 30, 2016, the Company granted under the Anika Therapeutics Second Amended and Restated 2003 Stock Option and Incentive Plan (the “Plan”) a total of 60,300 shares of stock options. During the nine-month period ended September 30, 2016, the Company granted under the Plan a total of 392,005 shares of stock options including 46,300 RSAs and 11,805 RSUs. All of the RSUs were granted to directors of the Company and vest over a one-year period. The stock options and RSAs granted to employees generally become exercisable or vest ratably over a four-year period.

A portion of the stock options granted during the nine-month period ended September 30, 2016 contained certain performance features, as compared to established targets, 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.



**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,	
	2016	2015	2016	2015
Shares used in the calculation of basic earnings per share	14,625	14,967	14,726	14,945
Effect of dilutive securities:				
Stock options, SARs, RSAs, and RSUs	452	349	437	366
Diluted shares used in the calculation of earnings per share	15,077	15,316	15,163	15,311

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 earnings per share because the awards' impact on earnings per share was anti-dilutive. Equity awards of 0.2 million shares were outstanding for the three- and nine-month periods ended September 30, 2015 and were not included in the computation of diluted earnings per share because the awards' impact on earnings per share was 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 an initial 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. This was approximately 70% of the total number of shares repurchased under the ASR Agreement.

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 sheet 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, 2016	December 31, 2015
Raw materials	\$ 5,840	\$ 5,780
Work-in-process	5,844	5,656
Finished goods	6,336	3,502
Total	\$ 18,020	\$ 14,938

Inventories are stated at the lower of cost or net realizable value, with cost being determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead. Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use and future economic benefit.

## 9. Intangible Assets

In connection with the 2009 acquisition of Anika Therapeutics S.r.l. (“Anika S.r.l.”), the Company acquired various intangible assets and goodwill. The Company evaluated the various intangible assets and related cash flows from these intangible assets, as well as the useful lives and amortization methods related to these intangible assets. The in-process research and development (“IPR&D”) intangible assets initially have indefinite lives and are reviewed periodically to assess the project status, valuation, and disposition, including write-off(s) for abandoned projects. Until such determination is made, they are not amortized.

Intangible assets as of September 30, 2016 and December 31, 2015 consist of the following:

		September 30, 2016			December 31, 2015		
	Gross Value	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life	
Developed technology	\$ 17,100	\$(2,985)	\$ (6,598 )	\$ 7,517	\$ 7,959	15	
In-process research & development	4,406	(1,235)	-	3,171	3,099	Indefinite	
Distributor relationships	4,700	(415 )	(4,285 )	-	-	5	
Patents	1,000	(179 )	(369 )	452	473	16	
Eleves trade name	1,000	-	(969 )	31	125	9	
Total	\$ 28,206	\$(4,814)	\$ (12,221 )	\$ 11,171	\$ 11,656		

The aggregate amortization expense related to intangible assets was \$0.3 million for the three-month periods ended September 30, 2016 and 2015, respectively. The aggregate amortization expense related to intangible assets was \$0.8 million for the nine-month periods ended September 30, 2016 and 2015.

## 10. Goodwill

Through September 30, 2016, 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, 2016	Twelve Months Ended December 31, 2015
Balance, beginning	\$ 7,482	\$ 8,339
Effect of foreign currency adjustments	208	(857 )
Balance, ending	\$ 7,690	\$ 7,482

**11. Accrued Expenses**

Accrued expenses consist of the following:

	September 30, 2016	December 31, 2015
Compensation and related expenses	\$ 2,647	\$ 3,082
Facility construction costs	336	415
Research grants	488	381
Professional fees	851	210
Clinical trial costs	333	252
Other	768	438
Total	\$ 5,423	\$ 4,778

**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. 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, 2016 or December 31, 2015, respectively, and has no history of claims paid.

The Company is also involved in various legal proceedings arising in the normal 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, 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. will lease 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 is expected to commence during the first quarter of 2017 once construction of the facility is completed. 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 \$0.4 million.

Construction of the new facility began in the first quarter of 2016 and is expected to be completed in early 2017. During the period of construction the Company is considered the deemed owner of the facility. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in the Company's consolidated balance sheet. As of September 30, 2016, the Company has recorded a construction-in-process asset of approximately \$2.4 million. This includes \$1.9 million incurred by ZIP for the construction of the new facility, which was recorded as a facility lease obligation within other long-term liabilities on the balance sheet.

### **14. Income Taxes**

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. Provisions for income taxes were \$4.8 million and \$11.4 million for the three- and nine-month periods ended September 30, 2015, based on effective tax rates of 36.4% and 36.7%, respectively. The increase in income taxes for the nine-month period ended September 30, 2016 resulted from higher income before income taxes 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, 2016, as compared to the same periods in 2015, was primarily due to an increase in the expected tax credit for research and development expenditures.

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. The Company's filings from 2013 through the present tax year remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The Company currently has tax audits in progress in the United States and Italy which we do not anticipate will have a material impact on its financial statements. The Company's filings from 2010 through the present tax year remain subject to

examination by the appropriate governmental authorities in Italy.

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 carryforward. The Company concluded that the positive evidence outweighs the negative evidence and, thus, those deferred tax assets are realizable on a “more likely than not” basis. As such, the Company did not record a valuation allowance at September 30, 2016 or December 31, 2015.

## 15. Segment and Geographic Information

The Company has one reportable operating segment, for the purposes of assessing performance and deciding how to allocate resources.

Product revenue by product group is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Orthobiologics	\$22,428	\$20,461	\$65,319	\$51,717
Surgical	1,173	1,413	3,924	4,450
Dermal	594	412	1,558	1,132
Other	1,588	1,390	3,835	4,790
Product Revenue	\$25,783	\$23,676	\$74,636	\$62,089

Total revenue by geographic location and as a percentage of overall total revenue for the three- and nine-month periods ended September 30, 2016 and 2015 are as follows:

	Three Months Ended September 30,			
	2016		2015	
	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
Geographic Location:				
United States	\$21,126	82 %	\$19,239	81 %
Europe	2,703	10 %	1,977	8 %
Other	1,960	8 %	2,465	11 %
Total Revenue	\$25,789	100 %	\$23,681	100 %

	Nine Months Ended September 30,			
	2016		2015	
	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
Geographic Location:				
United States	\$61,032	82 %	\$51,048	82 %
Europe	8,240	11 %	6,294	10 %
Other	5,381	7 %	4,763	8 %
Total Revenue	\$74,653	100 %	\$62,105	100 %





**ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS  
2. OF OPERATIONS (amounts in thousands, except per share amounts or as otherwise noted)**

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 discussion contains forward-looking statements that involve risks, uncertainties, and assumptions that could cause our actual results to differ materially from our expectations. Words such as “will,” “likely,” “may,” “believe,” “expect,” “anticipate,” “intend,” “seek,” “designed,” “develop,” “future,” “can,” “could,” and other expressions that are predictions of or indicate future events and trends, and which do not relate to historical matters, are intended to identify such forward-looking statements. These statements are likely to relate to, among other things, our goals, plans and projections regarding our financial position, results of operations, cash flows, market position, product development, product approvals, sales efforts, expenses, performance, and results related to current or anticipated products. You should carefully consider forward-looking statements and understand that such statements may be affected by inaccurate assumptions and may involve a variety of risks and uncertainties, known and unknown, including, among others, risks related to competition in the medical device industry, reduction or interruption in our supply, quality problems, decreasing prices, changes in applicable tax rates, adverse regulatory action, health care policy changes, international operations, or disruption of our current plans and operations, as well as those factors described in Part II, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2015, and as may be updated in our subsequent Quarterly Reports on Form 10-Q. Consequently, no forward-looking statements can be guaranteed and actual results may vary materially, and you should take caution not to place undue reliance on such statements. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events, 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 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, Ophthalmic, and Veterinary. 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 are 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 improve the efficiency of our manufacturing process and to enhance our research and development capabilities, with the aim of accelerating future product development. We expect to expend approximately \$25 million on this project.

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, 2015, 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 a CINGAL phase III clinical trial and associated statistical analysis during the fourth quarter of 2014. During the first half of 2015, we completed a CINGAL retreatment study with patients who had participated in the phase III clinical trial and reported safety data related to the retreatment study. We received approval for CINGAL from Health Canada in November 2015 for the treatment of pain in osteoarthritis of the knee. In March 2016, we received CE Mark approval of CINGAL as a viscoelastic supplement or as a replacement for synovial fluid in human joints. We successfully achieved commercial launch of the product in Canada during May 2016 and in the European Union during June 2016. In the United States, after discussions with the 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 at the end of 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 strong, existing CINGAL pivotal study data. Once the final details are confirmed by CDER, we intend to submit an Investigational New Drug Application ("IND") and to commence this phase III clinical trial by early 2017.

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, HYALOBONE, a bone void filler, 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. We are also 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 those to the elbow, rotator cuff, and Achilles tendon. We submitted a CE Mark application for this treatment during the first quarter of 2016, and we expect approval of this application during the first half of 2017. Additionally, in the second quarter of 2016, we submitted an IDE to the FDA to conduct a phase III pivotal clinical trial for this treatment, which was approved by the FDA in June 2016.

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 as early as 2017.

**Results of Operations**

Three and Nine Months Ended September 30, 2016 Compared to Three and Nine Months Ended September 30, 2015

	Three Months Ended September 30,					Nine Months Ended September 30,				
	2016	2015	\$	%		2016	2015	\$	%	
			Inc/(Dec)	Inc/(Dec)				Inc/(Dec)	Inc/(Dec)	
	(in thousands, except percentages)					(in thousands, except percentages)				
Product revenue	\$25,783	\$23,676	\$ 2,107	9	%	\$74,636	\$62,089	\$ 12,547	20	%
Licensing, milestone and contract revenue	6	5	1	20	%	17	16	1	6	%
Total revenue	25,789	23,681	2,108	9	%	74,653	62,105	12,548	20	%
Operating expenses:										
Cost of product revenue	4,998	5,176	(178 )	(3	%)	16,488	14,764	1,724	12	%
Research & development	2,822	2,061	761	37	%	7,773	5,971	1,802	30	%
Selling, general & administrative	4,280	3,309	971	29	%	12,525	10,302	2,223	22	%
Total operating expenses	12,100	10,546	1,554	15	%	36,786	31,037	5,749	19	%
Income from operations	13,689	13,135	554	4	%	37,867	31,068	6,799	22	%
Interest income, net	93	34	59	174	%	214	82	132	161	%
Income before income taxes	13,782	13,169	613	5	%	38,081	31,150	6,931	22	%
Provision for income taxes	4,830	4,789	41	1	%	13,619	11,435	2,184	19	%
Net income	\$8,952	\$8,380	\$ 572	7	%	\$24,462	\$19,715	\$ 4,747	24	%
Product gross profit	\$20,785	\$18,500	\$ 2,285	12	%	\$58,148	\$47,325	\$ 10,823	23	%
Product gross margin	81	%	78	%		78	%	76	%	

*Product Revenue*

Product revenue for the quarter ended September 30, 2016 was \$25.8 million, an increase of 9% as compared to \$23.7 million for the quarter ended September 30, 2015. Product revenue for the nine-month period ended September 30, 2016 was \$74.6 million, an increase of 20% as compared to \$62.1 million for the nine-month period ended September 30, 2015. For the three- and nine-month periods ended September 30, 2016, the increase in product revenue was mainly driven by the growth of our orthobiologics franchise with such increase being partially offset by a decrease in revenue from our surgical franchise. Included in product revenue for the first and second quarters of 2015 was approximately \$1.8 million of non-recurring true-up revenue related to a high end-user average selling price for MONOVISC products sold to our U.S. partner, DePuy Synthes Mitek Sports Medicine (“Mitek”), prior to the fourth quarter of 2014. The amount was agreed with Mitek during the second quarter of 2015, and MONOVISC product sold to Mitek after the third quarter of 2014 is not impacted by this arrangement.

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, 2016 and 2015:

Three Months Ended September 30,					
	2016	2015	\$	%	
			Inc/(Dec)	Inc/(Dec)	
<b>(in thousands, except percentages)</b>					
Orthobiologics	\$22,428	\$20,461	\$ 1,967	10	%
Surgical	1,173	1,413	(240 )	(17	%)
Dermal	594	412	182	44	%
Other	1,588	1,390	198	14	%
Total	\$25,783	\$23,676	\$ 2,107	9	%

Nine Months Ended September 30,					
	2016	2015	\$	%	
			Inc/(Dec)	Inc/(Dec)	
<b>(in thousands, except percentages)</b>					
Orthobiologics	\$65,319	\$51,717	\$ 13,602	26	%
Surgical	3,924	4,450	(526 )	(12	%)
Dermal	1,558	1,132	426	38	%
Other	3,835	4,790	(955 )	(20	%)
Total	\$74,636	\$62,089	\$ 12,547	20	%

### *Orthobiologics*

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 10% and 26% for the three- and nine-month periods ended September 30, 2016, respectively, as compared to the same periods in 2015. The growth in the three- and nine-month periods ending September 30, 2016 was primarily due to an increase in MONOVISC revenue in the United States. Both Orthovisc and Monovisc unit volumes increased during the three- and nine- months ended September 30, 2016. This volume gain was partially offset by the impact of pricing concessions made by our U.S. commercial partner Mitek, which were aimed at growing U.S. market share. Internationally, we experienced a 27% increase in orthobiologics revenue for the nine-month period ended September 30, 2016, as compared to the same period in 2015. We expect orthobiologics revenue to continue to grow for the remainder of 2016, led by increased MONOVISC revenue in the U.S. and international markets, 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 decreased 17% and 12% for the three- and nine-month periods ended September 30, 2016 to \$1.2 million and \$3.9 million, respectively, as compared to the same periods in 2015. The decrease in surgical product revenue for the three- and nine-month periods was primarily due to a decrease in sale to our worldwide ENT commercial partner. We expect surgical product revenue to decrease moderately for the full-year 2016, as compared to 2015.

### *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, 2016, dermal product sales increased 44% and 38%, respectively, as compared to the same periods in 2015. This increase reflects rising domestic and international end-user demand, as well as order timing by our distribution partners. We expect advanced wound care revenue to increase for the full-year 2016, as compared to 2015, primarily due to increased end-user demand, increased U.S. reimbursement coverage, and geographic expansion, particularly in the U.S., European, and Latin American markets.

### *Other*

Other product revenue includes revenues from our ophthalmic and veterinary franchises. Product revenue from each of these franchises increased for the three-month period ended September 30, 2016 while decreasing for the nine-month period then ended, as compared to the same periods in 2015. We expect other product revenue to decrease for the full-year 2016, as compared to 2015, primarily as a result of lower veterinary revenue.

*Product gross profit and margin*

Product gross profit for the three- and nine-month periods ended September 30, 2016 increased \$2.3 million and \$10.8 million to \$20.8 and \$58.1 million, respectively, representing 81% and 78% of product revenue, respectively. Product gross profit for the three- and nine- months ended September 30, 2015 was \$18.5 million and \$47.3 million, or 78% and 76% of product revenue for each period, respectively. The increase in product gross margin for the three-month period ended September 30, 2016, as compared to the same period in 2015, was primarily attributable to the increase in production volume as compared to the prior year. This quarter's 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, 2016 were \$2.8 million and \$7.8 million, or 11% and 10% of total revenue for the respective periods, an increase of \$0.8 million and \$1.8 million, respectively, as compared to the same periods in 2015. The increase in research and development expenses was primarily due to the timing and the higher level of clinical activities associated with the HYALOFAST phase III study, which commenced in December 2015. Furthermore, we also increased our pre-clinical product development activities, including with respect to the CE Mark application and IDE for our program which seeks to utilize our proprietary HA technology to treat pain associated with common repetitive overuse injuries, such as those to the elbow, rotator cuff, and Achilles tendon. Research and development spending is expected to increase in 2016, and for the foreseeable future, as compared to 2015, as we further develop new products and initiate new clinical trials based on our existing technology assets, including HYALOFAST, CINGAL, as well as increase development activities for other products in our pipeline.



*Selling, general, and administrative*

Selling, general, and administrative (“SG&A”) expenses for the three- and nine-month periods ended September 30, 2016 were \$4.3 million and \$12.5 million, representing 17% of total revenue for both periods, an increase of \$1.0 million and \$2.2 million, respectively, as compared to the same periods in 2015. SG&A expenses increased for the three- and nine-month periods ending September 30, 2016 primarily as a result of increases in personnel related costs, marketing initiatives to support CINGAL international launches, and external professional fees. We expect selling, general, and administrative expenses for 2016 will increase in comparison to 2015 to reflect the support required to grow our business, both domestically and internationally.

*Income taxes*

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. Provisions for income taxes were \$4.8 million and \$11.4 million for the three- and nine-month periods ended September 30, 2015, based on effective tax rates of 36.4% and 36.7%, respectively. The increase in income taxes for the three- and nine-month period ended September 30, 2016 resulted from higher income before income taxes as compared to the same periods in the prior year. The net decrease in the effective tax rate for the three- and nine-month period ended September 30, 2016, as compared to the same period in 2015, was primarily due to an increase in the expected tax credit for research and development expenditures.

*Liquidity and Capital Resources*

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 \$120.3 million and \$138.5 million at September 30, 2016 and December 31, 2015, respectively. Working capital totaled approximately \$153.5 million at September 30, 2016 and \$159.2 million at December 31, 2015. We believe that we have adequate financial resources to support our business for at least the next twelve months.

Cash provided by operating activities was \$17.9 million for the nine months ended September 30, 2016, as compared to cash provided by operating activities of \$23.8 million for the same period in 2015. The decrease in cash provided by operations for the nine months ended September 30, 2016, as compared to the same period in 2015, was primarily related to planned inventory build resulting from the transfer of outsourced contract manufacturing from Italy to our Bedford, Massachusetts facility, and a decrease in income taxes payable and accounts payable due to the timing of payments.

Cash used in investing activities was \$7.1 million for the nine months ended September 30, 2016, as compared to cash used in investing activities of \$17.3 million for the same period in 2015. The decrease in cash used in investing activities was primarily the result of the purchase of investments offset by maturities of investments during the first three quarters of 2016, as well as increased expenditures on capital equipment. We expect an increase in investing activities for the full year 2016 in comparison to 2015 as a result of our on-going project to establish the additional manufacturing capabilities at the Bedford, Massachusetts facility required to manufacture our HYAFF-based products, which were previously manufactured by a third party in Italy. During the quarter ended September 30, 2016, we expended approximately \$0.9 million for this project. We expect to expend approximately an additional \$4.2 million on this project over the course of the next nine months.

Cash used in financing activities was \$23.6 million for the nine months ended September 30, 2016, as compared to cash provided by financing activities totaling \$2.0 million for the same period in 2015. The increase in cash used in financing activities for the nine months ended September 30, 2016 was primarily attributable to the ASR Agreement to purchase \$25.0 million of shares of our common stock. Pursuant to the terms of the ASR Agreement, we paid Morgan Stanley \$25.0 million in cash and received a total delivery of 531,067 shares of our common stock at an average repurchase price of \$47.08 during the nine-month period ended September 30, 2016.

#### *Critical Accounting Estimates*

There were no other significant changes in our critical accounting estimates during the three months ended September 30, 2016, as compared to 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, 2015.

### ***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, 2015 and 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” in our Annual Report on Form 10-K for the year ended December 31, 2015. We had no material changes outside the ordinary course to our contractual obligations, as reported in our 2015 Annual Report on Form 10-K, during the first nine months of 2016.

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, 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, 2015. There have been no material changes in the first nine months of 2016 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.

Changes  
in internal  
(b) controls  
over  
financial  
reporting.

There  
were no  
changes  
in our  
internal  
control  
over  
financial  
reporting  
during the  
three-month  
period  
ended  
September  
30, 2016  
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 normal 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, 2015.



**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, 2015. 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, 2015, 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 facing our Company. 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS****Issuer Purchases of Equity Securities**

The following table provides information about purchases by us during the quarter ended September 30, 2016 of shares of our common stock.

Following is a summary of stock repurchases for the three months ended September 30, 2016:

Period	Total Number of Shares Repurchased <sup>(1)</sup>	Average Price Paid per Share <sup>(1)</sup>	Total Number of Shares Repurchased as Part of Publicly Announced Program <sup>(1)</sup>	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program <sup>(1)</sup>
July 1 to 31, 2016	-	-	-	\$ 7,500
August 1 to 31, 2016	153,912	\$ 47.08	531,067	-
September 1 to 30, 2016	-	-	-	-
Total	-	-	-	-

(1) On March 2, 2016, we publicly announced that on February 26, 2016 we had entered into the ASR Agreement to repurchase an aggregate of \$25.0 million of our common stock. During the first quarter of 2016, 377,155 shares were delivered to us under the ASR Agreement, constituting the initial delivery of shares under the ASR

Agreement. Pursuant to the terms of the ASR Agreement, the final number of shares and the average purchase price per share were determined at the end of the applicable purchase period, which occurred on August 26, 2016 when we settled the approximately \$7.5 million remaining under the ASR Agreement. Based on the volume-weighted average price from the effective date of the ASR Agreement through August 26, 2016 less the applicable contractual discount, Morgan Stanley delivered 153,912 additional shares to us on August 31, 2016. In total, 531,067 shares were repurchased under the ASR Agreement at an average repurchase price of \$47.08. All shares were repurchased in accordance with the publicly announced program. Final settlement occurred on August 26, 2016, and we will not make further purchases under the program.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not Applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

### **ITEM 5. OTHER INFORMATION**

None.

## ITEM 6. EXHIBITS

### Exhibit No. Description

- |        |   |
|--------|---|
| (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  |
|        | The following materials from Anika Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, as filed with the SEC on October 31, 2016, formatted in XBRL (eXtensible Business Reporting Language), as follows:  |
| *101   | <ul style="list-style-type: none"> <li>i. Condensed Consolidated Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015 (unaudited)</li> <li>ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2016 and September 30, 2015 (unaudited)</li> <li>iii. Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and September 30, 2015 (unaudited)</li> <li>iv. Notes to Condensed Consolidated Financial Statements (unaudited)</li> </ul> |

\* 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 31, 2016 By: /s/ SYLVIA CHEUNG

Sylvia Cheung

*Chief Financial Officer*

(Authorized Officer and Principal Financial Officer)