

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

**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 June 30, 2016**

**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.**

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

(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

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

As of July 28, 2016 there were 14,777,663 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>Financial Statements (unaudited):</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2016 and 2015</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015</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>13</u>
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>18</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>18</u>
<u>Part II</u>	
<u>Other Information</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>19</u>
<u>Item 1A.</u>	
<u>Risk Factors</u>	<u>19</u>
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>19</u>
<u>Item 3.</u>	
<u>Defaults Upon Senior Securities</u>	<u>20</u>
<u>Item 4.</u>	
<u>Mine Safety Disclosures</u>	<u>20</u>
<u>Item 6.</u>	
<u>Exhibits</u>	<u>20</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 share data and per share data)

(unaudited)

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$89,125	\$110,707
Investments	22,500	27,751
Accounts receivable, net of reserves of \$220 and \$167 at June 30, 2016 and December 31, 2015, respectively	24,597	21,652
Inventories	17,264	14,938
Prepaid expenses and other current assets	1,158	1,385
Total current assets	154,644	176,433
Property and equipment, net	49,198	40,108
Long-term deposits and other	69	69
Intangible assets, net	11,259	11,656
Goodwill	7,568	7,482
Total Assets	\$222,738	\$235,748
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$3,294	\$8,302
Accrued expenses and other current liabilities	6,638	4,778
Income taxes payable	591	4,198
Total current liabilities	10,523	17,278
Other long-term liabilities	1,173	781
Long-term deferred revenue	56	66
Deferred tax liability	6,570	6,775
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	-	-
Common stock, \$.01 par value; 60,000,000 and 30,000,000 shares authorized, 14,777,663 and 15,036,808 shares issued and outstanding at June 30, 2016 and December 31, 2015,	148	150

respectively

Additional paid-in-capital	59,506	81,685
Accumulated other comprehensive loss	(6,410 )	(6,649 )
Retained earnings	151,172	135,662
Total stockholders' equity	204,416	210,848
Total Liabilities and Stockholders' Equity	\$222,738	\$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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Product revenue	\$26,575	\$22,898	\$48,853	\$38,413
Licensing, milestone and contract revenue	6	6	11	11
Total revenue	26,581	22,904	48,864	38,424
Operating expenses:				
Cost of product revenue	6,065	5,275	11,490	9,588
Research & development	2,792	1,812	4,951	3,910
Selling, general & administrative	4,255	3,388	8,245	6,993
Total operating expenses	13,112	10,475	24,686	20,491
Income from operations	13,469	12,429	24,178	17,933
Interest income, net	49	24	121	48
Income before income taxes	13,518	12,453	24,299	17,981
Provision for income taxes	4,903	4,634	8,789	6,646
Net income	\$8,615	\$7,819	\$15,510	\$11,335
Basic net income per share:				
Net income	\$0.59	\$0.52	\$1.05	\$0.76
Basic weighted average common shares outstanding	14,679	14,961	14,778	14,934
Diluted net income per share:				
Net income	\$0.57	\$0.51	\$1.02	\$0.74
Diluted weighted average common shares outstanding	15,111	15,336	15,210	15,332
Net income	\$8,615	\$7,819	\$15,510	\$11,335
Other comprehensive income (loss):				
Unrealized gain (loss) on securities, net of tax	-	(3 )	-	(3 )
Foreign currency translation adjustment	(536 )	420	238	(1,828 )
Total other comprehensive income (loss)	(536 )	417	238	(1,831 )
Comprehensive income	\$8,079	\$8,236	\$15,748	\$9,504

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)

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net income	\$15,510	\$11,335
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,901	1,827
Stock-based compensation expense	1,478	1,064
Deferred income taxes	(252 )	(428 )
Provision for doubtful accounts	52	-
Provision for inventory	181	68
Tax benefit from equity awards	(419 )	(934 )
Changes in operating assets and liabilities:		
Accounts receivable	(2,932 )	(2,389 )
Inventories	(2,438 )	496
Prepaid expenses, other current and long-term assets	186	459
Accounts payable	(4,252 )	559
Accrued expenses and other current liabilities	446	(264 )
Deferred revenue	(45 )	(5 )
Income taxes payable	(3,169 )	3,194
Other long-term liabilities	396	(98 )
Net cash provided by operating activities	6,643	14,884
Cash flows from investing activities:		
Proceeds from maturity of investments	27,750	10,250
Purchase of investments	(22,499 )	(22,018 )
Purchase of property and equipment	(9,869 )	(1,134 )
Net cash used in investing activities	(4,618 )	(12,902 )
Cash flows from financing activities:		
Repurchases of common stock	(25,000 )	-
Proceeds from exercise of equity awards	922	969
Tax benefit from equity awards	419	934
Net cash (used in) provided by financing activities	(23,659 )	1,903
Exchange rate impact on cash	52	(121 )

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

Increase (decrease) in cash and cash equivalents	(21,582 )	3,764
Cash and cash equivalents at beginning of period	110,707	100,156
Cash and cash equivalents at end of period	\$89,125	\$103,920
Supplemental disclosure of cash flow information:		
Non-cash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$2,128	\$116

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 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 by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. The Company has over two decades of expertise developing, manufacturing, and commercializing more than 20 products, in markets across the globe, based on the Company's proprietary hyaluronic acid technology. The Company's orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States, among others) products to alleviate pain and restore joint function by replenishing depleted HA and aiding 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 June 30, 2016, the results of its operations for the three- and six-month periods ended June 30, 2016 and 2015, and cash flows for the six-month periods ended June 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 six-month periods ended June 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. 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 - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The new standard 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. The new standard will be effective for us on January 1, 2020. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

#### *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 adoption of this amendment 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 \$22.5 million and \$25.8 million at June 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 June 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 Identifiable Assets		
		Significant Other Significant Inputs Unobservable Inputs		
		(Level 1) (Level 2) (Level 3)		
June 30, 2016				
Cash equivalents:				
Money market funds	\$ 67,001	\$ -	\$ 67,001	\$ -
Investments:				
Bank certificates of deposit	\$ 22,500	\$ -	\$ 22,500	\$ -

		Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identifiable Assets		
		Significant Other Significant Inputs Unobservable Inputs		
		(Level 1) (Level 2) (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 six-month periods ended June 30, 2016 and 2015, respectively, was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,			
	2016		2015	
Risk free interest rate	0.94%	- 1.40%	1.15%	- 1.46%
Expected volatility	49.47%	- 51.61%	53.15%	- 54.65%
Expected life (years)	4.5		4.5	
Expected dividend yield	0.00%		0.00%	

The Company recorded \$0.7 million and \$0.5 million of share-based compensation expense for the three-month periods ended June 30, 2016 and 2015, respectively, for equity compensation awards. The Company recorded \$1.5 million and \$1.1 million of share-based compensation expense for the six-month periods ended June 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 June 30, 2016, the Company granted under the Equity Incentive Plan (“Plan”) a total of 43,000 stock options. During the six-month period ended June 30, 2016, the Company granted under the Plan a total of 331,705 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 four years from the date of grant.

A portion of the stock options granted during the six-month period ended June 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Shares used in the calculation of basic earnings per share	14,679	14,961	14,778	14,934
Effect of dilutive securities:				
Stock options, SARs, and RSAs	432	375	432	398
Diluted shares used in the calculation of earnings per share	15,111	15,336	15,210	15,332

Equity awards of 0.3 million shares were outstanding for the three- and six-month periods ended June 30, 2016 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 six-month periods ended June 30, 2015, respectively, 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 377,155 shares of the Company's common stock on February 29, 2016 based on a closing market price of \$46.40 and the applicable contractual

discount. This is approximately 70% of the total number of shares of expected to be repurchased under the ASR Agreement. These shares are held by the Company as authorized but unissued shares pursuant to Massachusetts law. The initial delivery of shares resulted in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted net income per share.

As of June 30, 2016, the Company has 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 will be determined at the end of the applicable purchase period, which is expected to occur in the third quarter of 2016. Upon settlement of the ASR Agreement, the Company may receive additional shares or be required to either pay additional cash or deliver shares of our common stock (at its option) to Morgan Stanley, based on the forward price. If the ASR Agreement had been settled as of June 30, 2016, based on the volume-weighted average price since the effective date of the ASR Agreement, Morgan Stanley would have been required to deliver approximately 0.2 million additional shares to the Company. However, the Company cannot predict the final number of shares to be received, or delivered, by it under the ASR Agreement, and, as such, these shares are not included in the calculation of diluted weighted-average common shares outstanding during the period because the effect is anti-dilutive.

**8. Inventories**

Inventories consist of the following:

	June 30, 2016	December 31, 2015
Raw materials	\$6,812	\$5,780
Work-in-process	6,140	5,656
Finished goods	4,312	3,502
Total	\$17,264	\$14,938

Inventories are stated at the lower of cost or market, 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 June 30, 2016 and December 31, 2015 consist of the following:

	June 30, 2016				December 31, 2015		
	Gross Value	Accumulated Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life	
Developed technology	\$17,100	\$(3,108)	\$(6,373)	\$7,619	\$7,959	15	
In-process research & development	4,406	(1,286)	-	3,120	3,099	Indefinite	
Distributor relationships	4,700	(415)	(4,285)	-	-	5	
Patents	1,000	(186)	(357)	457	473	16	
Eleless trade name	1,000	-	(937)	63	125	9	
Total	\$28,206	\$(4,995)	\$(11,952)	\$11,259	\$11,656		

The aggregate amortization expense related to intangible assets was \$0.3 million for the three-month periods ended June 30, 2016 and 2015, respectively. The aggregate amortization expense related to intangible assets was \$0.6 million and \$0.5 million for the six-month periods ended June 30, 2016 and 2015, respectively.

## 10. Goodwill

Through June 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:

	Six Months Ended June 30, 2016	Twelve Months Ended December 31, 2015
Balance, beginning	\$ 7,482	\$ 8,339
Effect of foreign currency adjustments	86	(857 )
Balance, ending	\$ 7,568	\$ 7,482

**11. Accrued Expenses**

Accrued expenses consist of the following:

	June 30, 2016	December 31, 2015
Compensation and related expenses	\$2,416	\$ 3,082
Facility construction costs	1,769	415
Research grants	481	381
Professional fees	889	210
Clinical trial costs	339	252
Other	744	438
Total	\$6,638	\$ 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 June 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 fourth quarter of 2016 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 late 2016. 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 June 30, 2016, the Company has recorded a construction-in-process asset of approximately \$0.9 million. This includes \$0.5 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 \$4.9 million and \$8.8 million for the three- and six-month periods ended June 30, 2016, based on effective tax rates of 36.3% and 36.2%, respectively. Provisions for income taxes were \$4.6 million and \$6.6 million for the three- and six-month periods ended June 30, 2015, based on effective tax rates of 37% for both periods. The increase in income taxes for the three- and six-month period ended June 30, 2016 resulted from higher net income as compared to the same periods in the prior year. The net decrease in the effective tax rate for the three- and six-month period ended June 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.

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 2012 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 a tax audit in progress in the United States and does not anticipate that the audit 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 June 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Orthobiologics	\$ 23,304	\$ 19,283	\$ 42,891	\$ 31,255
Surgical	1,433	1,647	2,751	3,037
Dermal	582	303	963	719
Other	1,256	1,665	2,248	3,402
Product Revenue	\$ 26,575	\$ 22,898	\$ 48,853	\$ 38,413

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

	Three Months Ended June 30,			
	2016	2015		
	Total	Percentage of Revenue	Total	Percentage of Revenue
Geographic Location:				



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

United States	\$21,895	82	%	\$19,218	84	%
Europe	2,977	11	%	2,331	10	%
Other	1,709	7	%	1,355	6	%
Total Revenue	\$26,581	100	%	\$22,904	100	%

Six Months Ended June 30,

2016

2015

Total	Percentage of	Total	Percentage of
Revenue	Revenue	Revenue	Revenue

Geographic Location:

United States	\$39,906	82	%	\$31,809	83	%
Europe	5,542	11	%	4,317	11	%
Other	3,416	7	%	2,298	6	%
Total	\$48,864	100	%	\$38,424	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 by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. We have over two decades of expertise developing, manufacturing, and commercializing our products, in markets across the globe, based on our proprietary hyaluronic acid (“HA”) technology. Our orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States, among others) products to alleviate pain and restore joint function by replenishing depleted HA and aiding 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 currently are manufactured by 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 in relation to clinical trials, in the future.

Our second single-injection osteoarthritis product under development 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 the 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, and preliminary indications from CDER suggested that additional clinical work may be required. We are employing multiple approaches to obtain definitive feedback with respect to our prospective NDA, and we plan to meet with the FDA to collaboratively discuss this topic.

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 Six Months Ended June 30, 2016 Compared to Three and Six Months Ended June 30, 2015

	Three Months Ended June 30,				Six Months Ended June 30,			
	2016	2015	\$	%	2016	2015	\$	%
			Inc/(Dec)	Inc/(Dec)			Inc/(Dec)	Inc/(Dec)
	(in thousands, except percentages)				(in thousands, except percentages)			
Product revenue	\$26,575	\$22,898	\$3,677	16 %	\$48,853	\$38,413	\$10,440	27 %
Licensing, milestone and contract revenue	6	6	-	0 %	11	11	-	0 %
Total revenue	26,581	22,904	3,677	16 %	48,864	38,424	10,440	27 %
Operating expenses:								
Cost of product revenue	6,065	5,275	790	15 %	11,490	9,588	1,902	20 %
Research & development	2,792	1,812	980	54 %	4,951	3,910	1,041	27 %
Selling, general & administrative	4,255	3,388	867	26 %	8,245	6,993	1,252	18 %
Total operating expenses	13,112	10,475	2,637	25 %	24,686	20,491	4,195	20 %
Income from operations	13,469	12,429	1,040	8 %	24,178	17,933	6,245	35 %
Interest income, net	49	24	25	105 %	121	48	73	152 %
Income before income taxes	13,518	12,453	1,065	9 %	24,299	17,981	6,318	35 %
Provision for income taxes	4,903	4,634	269	6 %	8,789	6,646	2,143	32 %
Net income	\$8,615	\$7,819	\$796	10 %	\$15,510	\$11,335	\$4,175	37 %
Product gross profit	\$20,510	\$17,623	\$2,887	16 %	\$37,363	\$28,825	\$8,538	30 %
Product gross margin	77%	77%			77%	75%		

*Product Revenue*

Product revenue for the quarter ended June 30, 2016 was \$26.6 million, an increase of 16% as compared to \$22.9 million for the quarter ended June 30, 2015. Product revenue for the six-month period ended June 30, 2016 was \$48.9 million, an increase of 27% as compared to \$38.4 million for the six-month period ended June 30, 2015. For the three-month period ended June 30, 2016, the increase in product revenue was driven by our orthobiologics franchise, and such increase was partially offset by decreases in our surgical and other product revenue as a result of the timing of orders for our veterinary products. For the six-month period ended June 30, 2016, we saw orthobiologics and dermal product revenue growth, both domestically and internationally, while surgical product revenue decreased slightly year-over-year primarily related to our ear, nose, and throat (“ENT”) anti-adhesion products. Included in product revenue for the second quarter of 2015 was approximately \$1.8 million of non-recurring 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.



The following tables present product revenue by group for the three- and six-month periods ended June 30, 2016 and 2015:

Three Months Ended June 30,					
	2016	2015	\$	%	
			Inc/(Dec)	Inc/(Dec)	
(in thousands, except percentages)					
Orthobiologics	\$23,304	\$19,283	\$ 4,021	21	%
Surgical	1,433	1,647	(214 )	(13	%)
Dermal	582	303	279	92	%
Other	1,256	1,665	(409 )	(25	%)
Total	\$26,575	\$22,898	\$ 3,677	16	%

Six Months Ended June 30,					
	2016	2015	\$	%	
			Inc/(Dec)	Inc/(Dec)	
(in thousands, except percentages)					
Orthobiologics	\$42,891	\$31,255	\$ 11,636	37	%
Surgical	2,751	3,037	(286 )	(9	%)
Dermal	963	719	244	34	%
Other	2,248	3,402	(1,154 )	(34	%)
Total	\$48,853	\$38,413	\$ 10,440	27	%

### *Orthobiologics*

Our orthobiologics franchise consists of our joint health and orthopedic products. Overall, sales increased 21% and 37% for the three- and six- month periods ended June 30, 2016, as compared to the same periods in 2015. The growth in the second quarter of 2016 reflected a significant increase in product purchases as compared with the same period in the prior year during which our U.S. commercial partner implemented a multi-month inventory reset program. Product sales to our U.S. commercial partner, Mitek, in the second quarter of 2016 increased by approximately \$2.7 million as compared to the second quarter of 2015. The volume gain was partially offset by the impact of pricing concessions by our commercial partner aimed at growing market share. More importantly, we also experienced growing end-user demand during the first half of 2016, resulting in increased revenue from worldwide orthobiologics sales, including a 47% increase in international orthobiologics revenue as compared to the same period in 2015. We expect orthobiologics revenue to continue to grow in 2016, led by increased MONOVISC revenue in the United States, 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 ENT disorders. Sales of our surgical products decreased 13% and 9% for the three- and six-month periods ended June 30, 2016 to \$1.4 million and \$2.8 million, respectively, as compared to the same periods in 2015. The decrease in surgical product revenue for the three- and six-month periods was primarily due to the unfavorable impact from foreign currency exchange rate fluctuations and the inventory releveling by our worldwide ENT commercial partner. As a result of these factors, we expect surgical product revenue to decrease moderately for the full-year 2016 compared to 2015.

#### *Dermal*

Our dermal franchise consists of advanced wound care products, which are based on the 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 six-month periods ended June 30, 2016, dermal product sales increased 92% and 34% 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 decreased for the three- and six-month periods ended June 30, 2016 as compared to the same periods in 2015, except for ophthalmic product revenue, which increased for the three-month period ended June 30, 2016. 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 six-month periods ended June 30, 2016 increased \$2.9 million and \$8.5 million to \$20.5 and \$37.4 million, respectively, or 77% of product revenue for both periods. Product gross profit for the three- and six- months ended June 30, 2015 was \$17.6 million and \$28.8 million, or 77% and 75% of product revenue for each period, respectively. The increase in product gross margin for the three-month period ended June 30, 2016, as compared to the same period in 2015, was primarily attributable to the overall product mix compared to the prior year, with sales of our higher-margin orthobiologics products accounting for a larger percentage of our total product sales. This quarter's product gross margin may not be indicative of the rest of the year due to dynamics such as future revenue mix.

*Research and development*

Research and development expenses for the three- and six-month periods ended June 30, 2016 were \$2.8 million and \$5.0 million, or 11% and 10% of total revenue for the respective periods, representing an increase of \$1.0 million for both periods 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, 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 six-month periods ended June 30, 2016 were \$4.3 million and \$8.2 million, representing 16% and 17% of total revenue for the periods, an increase of \$0.9 million and \$1.3 million, respectively, as compared to the same periods in 2015. SG&A expenses increased for the three- and six-month periods ending June 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 to reflect the support required to grow our business, both domestically and internationally.

*Income taxes*

Provisions for income taxes were \$4.9 million and \$8.8 million for the three- and six-month periods ended June 30, 2016, based on effective tax rates of 36.3% and 36.2%, respectively. Provisions for income taxes were \$4.6 million and \$6.6 million for the three- and six-month periods ended June 30, 2015, based on effective tax rates of 37% for both periods. The increase in income taxes for the three- and six-month period ended June 30, 2016 resulted from higher net income as compared to the same periods in the prior year. The net decrease in the effective tax rate for the three- and six-month period ended June 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 \$111.6 million and \$138.5 million at June 30, 2016 and December 31, 2015, respectively. Working capital totaled approximately \$144.1 million at June 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 \$6.6 million for the six months ended June 30, 2016, as compared to cash provided by operating activities of \$14.9 million for the same period in 2015. The decrease in cash provided by operations was due primarily to a decrease in net working capital, as compared to the same period in 2015, primarily related to the 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 due to the timing of payments.

Cash used in investing activities was \$4.6 million for the six months ended June 30, 2016, as compared to cash used in investing activities of \$12.9 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 half of 2016, as well as increased expenditures on capital equipment. We expect an increase in investing activities for the full year 2016 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 June 30, 2016, we expended approximately \$2.2 million for this project. We expect to expend approximately an additional \$5.1 million on this project over the course of the next 12 months.

Cash used in financing activities was \$23.7 million for the six months ended June 30, 2016, as compared to cash provided by financing activities totaling \$1.9 million for the same period in 2015. The increase in cash used in financing activities for the six months ended June 30, 2016 was primarily attributable to the Fixed Dollar Accelerated Share Repurchase Transaction 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 an initial delivery of 377,155 shares of our common stock on February 29, 2016 based on the closing market price of \$46.40 and the related applicable discount.

#### ***Critical Accounting Estimates***

There were no other significant changes in our critical accounting estimates during the three months ended June 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 six 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 six 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.

(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 June 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 June 30, 2016 of shares of our common stock.

Period	Total Number of Shares Repurchased (1)	Average Price Paid per Share (1)	Total Number of Shares Repurchased as Part of Publicly Announced Program (1)	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program (1)
April 1 to 30, 2016	-	-	-	\$ 7,500
May 1 to 31, 2016	-	-	-	7,500
June 1 to 30, 2016	-	-	-	7,500
Total	-	-	-	-

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 will be determined at the end of the applicable purchase period, which is expected to occur in or before August 2016. All shares were repurchased in accordance with the publicly announced program.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not Applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

### ITEM 6. EXHIBITS

#### Exhibit No. Description

*Restated Articles of Organization, as amended, of Anika Therapeutics, Inc. (with date of filing with Secretary of State of the Commonwealth of Massachusetts):*

- |      |   |
|------|---|
| 3.1a | Restated Articles of Organization (April 29, 1993), incorporated herein by reference to Exhibit 3.1a to Form 10-K, filed with SEC on March 13, 2015   |
| 3.1b | Certificate of Correction (November 10, 1993), incorporated herein by reference to Exhibit 3.1b to Form 10-K, filed with SEC on March 13, 2015  |
| 3.1c | Certificate of Vote of Directors Establishing a Series of a Class of Stock (May 18, 1995), incorporated herein by reference to Exhibit 3.1c to Form 10-K, filed with SEC on March 13, 2015  |
| 3.1d | Articles of Amendment (January 9, 1997), incorporated herein by reference to Exhibit 3.1 to Form 10-QSB, filed with SEC on January 14, 1997   |
| 3.1e | Certificate of Vote of Directors Establishing a Series of a Class of Stock (April 7, 1998), incorporated herein by reference to Exhibit 3.1e to Form 10-K, filed with SEC on March 13, 2015 |
| 3.1f | Articles of Amendment (June 3, 1998), incorporated herein by reference to Exhibit 3.1 to Form 10-QSB, filed with SEC on August 13, 1998   |
| 3.1g | Articles of Amendment (April 4, 2008), incorporated herein by reference to Exhibit 3.7 to Form 10-K, filed with SEC on March 9, 2009  |



Articles of Amendment (June 8, 2016)

\*3.1h

(31) Rule 13a-14(a)/15d-14(a) Certifications

20

- \*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 June 30, 2016, as filed with the SEC on August 1, 2016, formatted in XBRL (eXtensible Business Reporting Language), as follows:
- \*101

- i. Condensed Consolidated Balance Sheets as of June 30, 2016 (unaudited) and December 31, 2015 (unaudited)
- ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Six Months Ended June 30, 2016 and June 30, 2015 (unaudited)
- iii. Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2016 and June 30, 2015 (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: August 1, 2016 By: /s/ SYLVIA CHEUNG  
Sylvia Cheung  
Chief Financial Officer  
(Authorized Officer and Principal Financial Officer)

