

Anika Therapeutics, Inc.
Form 10-Q
July 31, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2018

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

For the transition period from to

Commission File Number 000-21326

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

04-3145961
(I.R.S. Employer Identification No.)

32 Wiggins Avenue, Bedford, Massachusetts 01730
(Address of Principal Executive Offices) (Zip Code)

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

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

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

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

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

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

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

As of July 25, 2018, there were 14,583,597 outstanding shares of Common Stock, par value \$.01 per share.

ANIKA THERAPEUTICS, INC.

TABLE OF CONTENTS

	Page
<u>Part I</u> <u>Financial Information</u>	
<u>Item 1.</u> <u>Financial Statements (unaudited):</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2018 and 2017</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and 2017</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>15</u>
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>20</u>
<u>Item 4.</u> <u>Controls and Procedures</u>	<u>20</u>
<u>Part II</u> <u>Other Information</u>	
<u>Item 1.</u> <u>Legal Proceedings</u>	<u>21</u>
<u>Item 1A.</u> <u>Risk Factors</u>	<u>21</u>
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>23</u>
<u>Item 6.</u> <u>Exhibits</u>	<u>24</u>
<u>Signatures</u>	<u>25</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)

ASSETS	June 30, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	\$126,047	\$133,256
Investments	13,250	24,000
Accounts receivable, net of reserves of \$1,862 and \$1,914 at June 30, 2018 and December 31, 2017, respectively	23,389	23,825
Inventories, net	24,060	22,035
Prepaid expenses and other current assets	4,244	3,211
Total current assets	190,990	206,327
Property and equipment, net	55,377	56,183
Other long-term assets	1,157	1,254
Intangible assets, net	9,876	10,635
Goodwill	8,013	8,218
Total assets	\$265,413	\$282,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$5,073	\$6,747
Accrued expenses and other current liabilities	7,459	6,326
Total current liabilities	12,532	13,073
Other long-term liabilities	882	660
Deferred tax liability	5,396	5,393
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250 shares authorized, no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	-	-
Common stock, \$.01 par value; 90,000 and 60,000 shares authorized, 14,584 and 14,688 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	146	147
Additional paid-in-capital	48,656	68,617
Accumulated other comprehensive loss	(5,115)	(4,784)
Retained earnings	202,916	199,511

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

Total stockholders' equity	246,603	263,491
Total liabilities and stockholders' equity	\$265,413	\$282,617

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

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Income

(in thousands, except per share data)

(unaudited)

	Three Months		Six Months Ended	
	Ended June 30,		June 30,	
	2018	2017	2018	2017
Product revenue	\$30,542	\$28,340	\$51,800	\$51,721
Licensing, milestone and contract revenue	6	5,122	12	5,127
Total revenue	30,548	33,462	51,812	56,848
Operating expenses:				
Cost of product revenue	8,152	6,315	15,996	12,398
Research & development	4,733	4,449	9,895	8,679
Selling, general & administrative	6,417	4,972	22,507	10,039
Total operating expenses	19,302	15,736	48,398	31,116
Income from operations	11,246	17,726	3,414	25,732
Interest and other income, net	290	16	385	74
Income before income taxes	11,536	17,742	3,799	25,806
Provision for income taxes	1,444	6,373	394	8,944
Net income	\$10,092	\$11,369	\$3,405	\$16,862
Basic net income per share:				
Net income	\$0.69	\$0.78	\$0.23	\$1.16
Basic weighted average common shares outstanding	14,652	14,588	14,666	14,582
Diluted net income per share:				
Net income	\$0.68	\$0.76	\$0.23	\$1.12
Diluted weighted average common shares outstanding	14,915	15,044	15,045	15,046
Net income	\$10,092	\$11,369	\$3,405	\$16,862
Foreign currency translation adjustment	(951)	1,289	(331)	1,581
Comprehensive income	\$9,141	\$12,658	\$3,074	\$18,443

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,	
	2018	2017
Cash flows from operating activities:		
Net income	\$3,405	\$16,862
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,920	2,022
Loss on disposal of fixed assets	172	-
Stock-based compensation expense	8,887	2,465
Deferred income taxes	63	589
Provision for doubtful accounts	(6)	(1)
Provision for inventory	3,993	287
Changes in operating assets and liabilities:		
Accounts receivable	1,926	(2,449)
Inventories	(5,990)	(1,741)
Prepaid expenses, other current and long-term assets	790	(155)
Accounts payable	(194)	2,362
Accrued expenses, other current and long-term liabilities	(100)	(813)
Income taxes	(1,803)	2,303
Net cash provided by operating activities	14,063	21,731
Cash flows from investing activities:		
Proceeds from maturity of investments	24,750	20,000
Purchase of investments	(14,000)	(24,500)
Purchase of property and equipment	(3,283)	(3,917)
Net cash provided by (used in) investing activities	7,467	(8,417)
Cash flows from financing activities:		
Repurchases of common stock	(30,000)	-
Cash paid for tax withheld on vested restricted stock awards	(1,735)	-
Proceeds from exercise of equity awards	2,886	209
Net cash (used in) provided by financing activities	(28,849)	209
Exchange rate impact on cash	110	90
(Decrease) Increase in cash and cash equivalents	(7,209)	13,613
Cash and cash equivalents at beginning of period	133,256	104,261
Cash and cash equivalents at end of period	\$126,047	\$117,874
Supplemental disclosure of cash flow information:		

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

Non-cash Investing Activities:

Purchases of property and equipment included in accounts payable and accrued expenses	\$462	\$1,193
---	-------	---------

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

ANIKA THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(unaudited)

1. Nature of Business

Anika Therapeutics, Inc. (the “Company”) is a global, integrated orthopedic and regenerative medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions with clinically meaningful therapies along the continuum of care, from palliative pain management to regenerative tissue repair. The Company has over two decades of global expertise developing, manufacturing, and commercializing products based on its proprietary Hyaluronic Acid (“HA”) technology. The Company’s orthopedic medicine portfolio includes ORTHOVISC, MONOVISC, and CINGAL, which alleviate pain and restore joint function by replenishing depleted HA, and HYALOFAST, a solid HA-based scaffold to aid cartilage repair and regeneration.

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

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) and in accordance with accounting principles generally accepted in the United States (“US GAAP”). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with US GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. The December 31, 2017 balances reported herein are derived from the audited consolidated financial statements. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the condensed consolidated financial position of the Company as of June 30, 2018, the results of its operations for the three- and six-month periods ended June 30, 2018 and 2017, and cash flows for the six-month periods ended June 30, 2018 and 2017.

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with the Company's annual financial statements filed with its Annual Report on Form 10-K for the year ended December 31, 2017. The results of operations for the three- and six-month periods ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018.

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

Recent Accounting Pronouncements

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

3. Revenue

The Company adopted the guidance in the FASB's Accounting Standards Codification (ASC) *Revenue from Contracts with Customers* (ASC 606) using the modified retrospective method effective January 1, 2018. The adoption of ASC 606 was applied to all contracts not completed as of the date of adoption. The adoption did not have a material impact on the amount and timing of revenue recognized in the condensed consolidated financial statements. The Company made no adjustments to our previously reported total and product revenue, as those periods continue to be presented in accordance with the Company's historical accounting practices under Topic, 605, *Revenue Recognition*.

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

Product Revenues

The Company sells its products principally to a number of distributors (i.e., its customers) under legally enforceable executed contracts. The Company's distributors subsequently resell the products to sub-distributors and health care providers, among others. The Company recognizes revenue from product sales when the distributor obtains control of the Company's product, which typically occurs upon shipment to the distributor, in return for agreed-upon fixed price consideration. Performance obligations are generally settled quickly after purchase order acceptance; therefore, the value of unsatisfied performance obligations at the end of any reporting period is generally immaterial.

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

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

context of the contract, revenue is deferred.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. As of June 30, 2018, deferred revenue was \$0.1 million.

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

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

License, Milestone and Contract Revenues

The Company has agreements with DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics, Inc. (“Mitek”) that include the grant of certain licenses, performance of development services, and supply of product. Revenues from the agreements with Mitek represent 72% and 73% of total Company revenues for the three- and six-month periods ended June 30, 2018, respectively. The Company has agreements with other customers that may include the delivery of a license and supply of product. The adoption of ASC 606 did not impact the accounting for these agreements.

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

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

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

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

	Three Months		Six Months Ended	
	Ended June 30,		June 30,	
	2018	2017	2018	2017
Orthobiologics	\$26,192	\$24,468	\$45,681	\$44,695
Surgical	1,263	1,335	2,509	2,631
Dermal	623	453	83	878

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

Other	2,464	2,084	3,527	3,517
Product Revenue	\$30,542	\$28,340	\$51,800	\$51,721

Total revenue by geographic location and as a percentage of overall total revenue for the three- and six-month periods ended June 30, 2018 and 2017 is as follows:

Geographic Location:	Three Months Ended June 30, 2018		2017	
	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
United States	\$24,773	81 %	\$27,447	82 %
Europe	3,498	11 %	4,060	12 %
Other	2,277	8 %	1,955	6 %
Total Revenue	\$30,548	100 %	\$33,462	100 %

	Six Months Ended June 30,		2017			
	2018				2017	
Geographic Location:	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue		
United States	\$41,682	81 %	\$46,377	82 %		
Europe	5,889	11 %	6,889	12 %		
Other	4,241	8 %	3,582	6 %		
Total Revenue	\$51,812	100 %	\$56,848	100 %		

On May 2, 2018, the Company publicly disclosed a voluntary recall of certain lots of its HYAFF-based products, HYALOFAST, HYALOGRAFT C, and HYALOMATRIX. The Company initiated the recall after internal quality testing, which indicated that the products were at risk of not maintaining certain measures throughout their entire shelf life. While there is no indication of any safety or efficacy issue related to the products at this time, the Company remains committed to the highest standards of quality and is removing the products from the field as a precautionary measure. During the three-month period ended March 31, 2018 the Company recorded a revenue reserve for this voluntary recall of \$1.1 million of which \$0.9 million was related to revenue recorded in prior periods. The adjustments related to the initial revenue reserve during the three-month period ended June 30, 2018 were immaterial. The revenue reserves impacted Dermal and Orthobiologics product groups and all geographic locations.

4. Investments

All of the Company's investments are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income, net of related income taxes. The Company held bank certificates of deposit of \$13.3 million and \$24.0 million as of June 30, 2018 and December 31, 2017, respectively. There were no unrealized gains or losses on the Company's available-for-sale securities as of June 30, 2018 or December 31, 2017.

5. Fair Value Measurements

The Company's investments are all classified within Levels 1 and 2 of the fair value hierarchy. The Company's investments classified within Level 1 of the fair value hierarchy are valued based on quoted prices in active markets. Level 2 investments are based on matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk. For cash and cash equivalents, current receivables, accounts payable, and interest accrual, the carrying amounts approximate fair value because of the short maturity of these instruments, and therefore fair value information is not included in the table below.

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

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

	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)	
	June 30, 2018			
Cash equivalents:				
Money market funds	\$17,366	\$17,366	\$ -	\$ -
U.S. Treasury Bills	43,596	43,596	-	-
Total cash equivalents	\$60,962	\$60,962	\$ -	\$ -
Investments:				
Bank certificates of deposit	\$13,250	\$-	\$ 13,250	\$ -

	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, 2017					
Cash equivalents:						
Money market funds	\$ 5,893	\$ 5,893	\$ -			\$ -
Bank certificates of deposit	500	-	500			-
Total cash equivalents	\$ 6,393	\$ 5,893	\$ 500			\$ -
Investments:						
Bank certificates of deposit	\$ 24,000	\$-	\$ 24,000			\$ -

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 six-month periods ended June 30, 2018 and 2017 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,			
	2018		2017	
Risk free interest rate	2.15%	-	2.75%	1.65% - 1.78%
Expected volatility	37.12%	-	40.81%	42.54% - 44.30%
Expected life (years)	4.0	-	4.5	4.0
Expected dividend yield	0.00%			0.00%

The Company recorded \$1.3 million of stock-based compensation expense for the three-month periods ended June 30, 2018 and 2017 for equity compensation awards. The Company recorded \$8.9 million and \$2.5 million of stock-based compensation expense for the six-month periods ended June 30, 2018 and 2017, respectively, for stock-based compensation awards. Upon the retirement of the Company’s former Chief Executive Officer on March 9, 2018, all of his outstanding stock-based compensation awards vested in full and became exercisable in accordance with their terms, resulting in a one-time expense of \$6.2 million that was fully recognized during the three-month period ended March 31, 2018.

The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to each of its employees as follows:

	Three Months		Six Months	
	Ended June 30,		Ended June 30,	
	2018	2017	2018	2017
Cost of product revenue	\$(28)	\$102	\$(244)	\$199
Research and development	241	153	451	163
Selling, general and administrative	1,109	1,029	8,680	2,103
Total stock-based compensation expense	\$1,322	\$1,284	\$8,887	\$2,465

The decrease in stock-based compensation expense within the cost of product revenue line item during the three- and six-month periods ended June 30, 2018 is due to forfeitures associated with unvested stock option awards from the resignation of a former executive.

The following table sets forth share information for equity awards granted and exercised during the three- and six-month periods ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Grants:				
Stock options	17,500	5,500	209,800	410,135
RSAs	-	-	64,578	-
RSUs	-	-	8,130	9,970
Exercises:				
Stock options	273,123	3,850	284,548	9,437
SARs	-	-	-	5,000

During the three- and six-month periods ended June 30, 2018 and 2017 the Company granted stock option awards to employees the majority of which become exercisable or vest ratably over a four-year and three-year period, respectively. In addition, the Company executed its annual grant of RSUs to non-employee directors each of which vests over a one-year period. On March 9, 2018, upon the vesting of certain RSAs, 32,541 shares with a total fair value of \$1.7 million were withheld for taxes and retired.

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Shares used in the calculation of basic earnings per share	14,652	14,588	14,666	14,582
Effect of dilutive securities:				
Stock options, SARs, and RSAs	263	456	379	464
Diluted shares used in the calculation of earnings per share	14,915	15,044	15,045	15,046

Stock options of 0.7 million shares were outstanding for the three-month periods ended June 30, 2018 and 2017, respectively, and were not included in the computation of diluted EPS because the awards' impact on EPS would have been anti-dilutive. Stock options of 0.6 million and 0.3 million shares were outstanding for the six-month period ended June 30, 2018 and 2017, respectively, and were not included in the computation of diluted EPS because the awards' impact on EPS would have been anti-dilutive.

On May 24, 2018, 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 \$30.0 million of shares of its common stock. Pursuant to the terms of the ASR Agreement, the Company delivered \$30.0 million cash to Morgan Stanley and received an initial delivery of 0.4 million shares of the Company's common stock on May 24, 2018 based on a closing market price of \$41.41 and the applicable contractual discount. This is approximately 60% of the then estimated total number of shares expected to be repurchased under the ASR Agreement. These shares were restored to the status of authorized but unissued shares. The initial delivery of shares resulted in an immediate reduction of the number of outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted net income per share on the effective date of the ASR Agreement.

As of June 30, 2018, the Company had approximately \$12.0 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. On July 16, 2018, pursuant to the terms of the ASR Agreement, Morgan Stanley accelerated the final settlement date forward from December 2018, and the final number of shares and the average purchase price was determined. Based on the volume-weighted average price since the effective date of the ASR Agreement, less the applicable contractual discount, Morgan Stanley delivered 0.4 million additional shares to the Company on July 19, 2018. In total, 0.8 million shares were repurchased under the ASR Agreement at an average repurchase price of \$37.18 per share. All shares were repurchased in accordance with the publicly announced program. Final settlement occurred on July 16, 2018, and the Company will not make further purchases under the program.

8. Inventories

Inventories consist of the following:

	June 30, 2018	December 31, 2017
Raw materials	\$12,582	\$11,296
Work-in-process	6,322	6,062
Finished goods	5,156	4,677
Total	\$24,060	\$22,035

As a result of the voluntary recall more fully described in Note 3, the Company recorded an inventory reserve of \$0.8 million for non-saleable inventory. In addition, the Company recorded an inventory reserve of \$1.7 million for certain HA raw materials, and it recorded a lower of cost or market adjustment of \$1.2 million for certain HYAFF-based products during the six-month period ended June 30, 2018.

9. Intangible Assets

Intangible assets as of June 30, 2018 and December 31, 2017 consisted of the following:

	June 30, 2018			December 31, 2017			Useful Life	
	Gross Value	Accumulated Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Accumulated Currency Translation Adjustment	Accumulated Amortization		Net Book Value
Developed technology	\$17,100	\$(2,704)	\$(8,210)	\$6,186	\$(2,550)	\$(7,723)	\$6,827	15
In-process research & development	4,406	(1,097)	-	3,309	(1,015)	-	3,391	Indefinite
Distributor relationships	4,700	(415)	(4,285)	-	(415)	(4,285)	-	5
Patents	1,000	(162)	(457)	381	(152)	(431)	417	16
Eleless trade name	1,000	-	(1,000)	-	-	(1,000)	-	9
Total	\$28,206	\$(4,378)	\$(13,952)	\$9,876	\$(4,132)	\$(13,439)	\$10,635	

The aggregate amortization expense related to intangible assets was \$0.3 million and \$0.2 million for the three-month periods ended June 30, 2018 and 2017, respectively. The aggregate amortization expense related to intangible assets was \$0.5 million for each of the six-month periods ended June 30, 2018 and 2017.

10. Goodwill

The Company completed its annual impairment review as of November 30, 2017 and concluded that no impairment in the carrying value of goodwill exists as of that date. Through June 30, 2018, there have been no 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:

	June 30, 2018
Balance at January 1, 2018	\$8,218
Effect of foreign currency adjustments	(205)
Balance at June 30, 2018	\$8,013

11. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2018	December 31, 2017
Compensation and related expenses	\$3,633	\$ 2,893
Clinical trial costs	867	2,318
Accrued liabilities related to product recall	1,181	-
Research grants	408	419
Professional fees	1,213	448
Deferred income	74	-
Other	83	248
Total	\$7,459	\$ 6,326

Included in Compensation and related expenses as of June 30, 2018 are the accrued and unpaid costs related to the retirement of the Company's former Chief Executive Officer as of March 9, 2018. Under the terms of his employment agreement, the former Chief Executive Officer is entitled to receive from the Company, as a result of his retirement, aggregate benefits of \$1.7 million over the 18-month period subsequent to March 9, 2018, among other benefits. On March 8, 2018 the Company entered into a \$0.3 million one-year, post-retirement consulting agreement with the former Chief Executive Officer to provide certain services as may be requested by the Company through February 28, 2019. The unpaid amounts under these agreements are included in accrued expenses and other long-term liabilities. As more fully described in Note 6, all of the former Chief Executive Officer's outstanding equity awards vested in full and became exercisable upon his retirement.

Accrued liabilities related to product recall includes amounts due to customers for estimated product returns as a result of the voluntary recall more fully described in Note 3 as well as an accrual of \$0.4 million for future expenses associated with the administration and remediation of the voluntary recall.

12. Commitments and Contingencies

In certain of its contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the specific product. The Company may also warrant that the products it manufactures do not infringe, violate, or breach any U.S. or international patent or intellectual property right, trade secret, or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligent acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure to these risks. Based on the Company's historical activity, in combination with its liability insurance coverage, the Company believes

the estimated fair value of these indemnification agreements is immaterial. The Company had no accrued warranties as of June 30, 2018 or December 31, 2017, respectively, and has no history of claims paid.

The Company is also involved from time-to-time 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 occasional legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flow.

13. Income Taxes

The provisions for income taxes were \$1.4 million and \$0.4 million for the three- and six- month periods ended June 30, 2018, based on effective tax rates of 12.5% and 10.4%, respectively. Provisions for income taxes were \$6.4 million and \$8.9 million for the three- and six- month periods ended June 30, 2017, based on effective tax rates of 35.9% and 34.7%, respectively. The net decrease in the effective tax rate for the three- and six- month periods ended June 30, 2018, as compared to the same periods in 2017, was primarily due to the reduction of Federal Corporate Income Tax rate as a result of the Tax Cuts and Jobs Act (“Tax Act”) tax reform legislation. This legislation makes significant changes to the U.S. tax law, including a reduction in the corporate tax rate from 35% to 21% starting in 2018. In addition, during the second quarter the Company realized windfall tax benefits related to exercises of employee equity awards resulting in a discrete period income tax benefit of \$1.3 million and a reduction in the effective tax rate of 11.3%.

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

In connection with the preparation of the financial statements, the Company assesses whether it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its net operating loss carry-forward. The Company has concluded that the positive evidence outweighs the negative evidence and, thus, the deferred tax assets not otherwise subject to a valuation allowance are realizable on a “more likely than not” basis. As such, the Company did not record a valuation allowance as of June 30, 2018 or December 31, 2017.

In accordance with Staff Accounting Bulletin No. 118, which provides guidance on accounting for the tax effects of the 2017 Tax Act, the Company has recorded a reasonable estimate of the impact on the consolidated financial statements. We will continue to assess forthcoming guidance and accounting interpretations on the effects of the Tax Act and expect to complete the analysis within the measurement period in accordance with the SEC guidance. The Company does not expect a significant adjustment to the recorded amounts.

14. Business Segment

The Company operates in a single segment engaged in the discovery, development, licensing, manufacturing, and sale of innovative medical therapies that improve the lives of patients with degenerative orthopedic diseases and traumatic conditions. The determination of a single segment is consistent with the financial information regularly reviewed by the Chief Executive Officer, who is the chief decision maker for the purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods. For further information on product and geographic revenues, see Note 3.

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

Please also refer to those factors described in Part II, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2017 and in Part II, Item 1A "Risk Factors" of this report for important factors that we believe could cause actual results to differ materially from those in our forward-looking statements. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Management Overview

We are a global, integrated orthopedic and regenerative medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions with clinically meaningful therapies along the continuum of care, from palliative pain management to regenerative tissue repair. We have over two decades of global expertise developing, manufacturing, and commercializing our products based on our proprietary hyaluronic acid ("HA") technology. Our orthopedic medicine portfolio includes ORTHOVISC, MONOVISC, and CINGAL, which alleviate pain and restore joint function by replenishing depleted HA, and HYALOFAST, a solid HA-based scaffold to aid cartilage repair and regeneration.

Our therapeutic offerings consist of products in the following areas: Orthobiologics, Dermal, Surgical, and Other, which includes our ophthalmic and veterinary products. All of our products are based on HA, a naturally occurring,

biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

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

Since our inception in 1992, we have utilized a commercial partnership model for the distribution of our products to end-users. Our strong, worldwide network of distributors has historically provided, and continues to provide, a solid foundation for our revenue growth and territorial expansion. We have made the strategic decision to commercialize, at least in part, 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 have made meaningful progress on our initiative to develop this functionality, but we have delayed additional pre-launch activities for CINGAL as we evaluate its regulatory pathway in the United States, as described below. We are also currently evaluating a potential hybrid commercial approach that would see us balance our direct model with a limited form of strategic partnership. For future products in the U.S. market, we intend to evaluate the appropriate commercial model for each on a case-by-case basis, based on market dynamics and other factors. These models could include direct sales, distribution partnerships, or a hybrid of those forms. We believe that the combination of the direct and distribution commercial models will maximize the revenue potential from our current and future product portfolio.

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, 2017, for a description of each of the above therapeutic areas, including the individual products.

Our notified body, which is responsible for performing a conformity assessment for MONOVISC in the European Union, advised us of the suspension of our CE Mark for MONOVISC as of March 27, 2018. This suspension resulted from changes in the regulatory environment in 2017 and administrative difficulties between our notified body and us related to our providing of the notified body with certain technical information for MONOVISC. This suspension was not related to any safety or efficacy issues associated with the product. On May 30, 2018, our notified body issued an updated CE Mark for MONOVISC. This matter did not impact our financial results in the quarter ended June 30, 2018 or in any prior periods, and we do not expect any impact on our financial results going forward.

On May 2, 2018, we publicly disclosed a voluntary recall of certain production lots of our HYAFF-based products, HYALOFAST, HYALOGRAFT C, and HYALOMATRIX. We communicated with all affected distributors in advance of that announcement, and we are taking all required or otherwise appropriate actions with respect to applicable regulatory bodies. We initiated the recall following internal quality testing, which indicated that the products were at risk of not maintaining certain measures throughout their entire shelf life. While there was no indication of any safety or efficacy issue related to the products, we are committed to the highest standards of quality and removed the products from the field as a precautionary measure. During the three-month period ended March 31, 2018 we recorded a revenue reserve for this voluntary recall of \$1.1 million of which \$0.9 million was related to revenue recorded in prior periods. The adjustments related to the initial revenue reserve during the three-month period ended June 30, 2018 were immaterial. As a result of the voluntary recall, we had an inventory charge of \$0.8 million for the related non-saleable inventory during the six-month period ended June 30, 2018. In addition, we accrued \$0.4 million for future expenses associated with the administration and remediation of the voluntary recall. As of June 30, 2018, a majority of the affected products had been returned with no material change to the related reserves. Based on the facts currently known to us, we believe we can resolve this matter and resume production and shipment of these products by the end of 2018.

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 in the near future to research and development activities, including in relation to preclinical activities and clinical trials. These activities are aimed at the delivery of a steady cascade of new product development and launches over the next several years.

Our second single-injection osteoarthritis product under development in the United States, 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, is our lead pipeline product and a critical component of our growth strategy. We completed an initial CINGAL Phase III clinical trial, including the associated statistical analysis for 368 enrolled patients, during the fourth quarter of 2014 with data indicating that the product met all primary and secondary endpoints relative to placebo set forth for the trial. During the first half of 2015, we completed a CINGAL retreatment study with 242 patients who had participated in the Phase III clinical trial and reported safety data related to the retreatment study. This initial Phase III clinical trial and the associated retreatment study supported the Health Canada and CE Mark approval of the product, and the commercial launch of the product in both Canada and the European Union occurred in the second quarter of 2016. In the United States, after discussions with the U.S. Food and Drug Administration (“FDA”) related to the regulatory pathway for CINGAL, we conducted a formal meeting with the FDA’s Office of Combination Products (“OCP”) to present and discuss our data in September 2015, and we submitted a formal request for designation with OCP a month later. In its response to our formal request for designation, OCP assigned the product to the FDA’s Center for Drug Evaluation and Research (“CDER”) as the lead agency center for premarket review and regulation. We then held discussions with CDER to understand the requirements for submitting a New Drug Application (“NDA”) for CINGAL. We held a meeting with CDER in September 2016 to align on an approval framework and on submission requirements for this NDA for CINGAL, including the execution of an additional Phase III clinical trial to supplement our existing CINGAL pivotal study data. We submitted an Investigational New Drug Application (“IND”) in late 2016, and discussions with CDER indicated that they did not have objections to our clinical protocol design. As a result, we commenced work on this second Phase III clinical trial (“CINGAL 16-02 Study”) in the first quarter of 2017, and the first patient was treated in the second quarter of 2017. Enrollment of the 576 patients in this second Phase III clinical trial was completed during October 2017, and we completed the six-month patient follow-up in April 2018. We received and analyzed the data from the CINGAL 16-02 Study during the second quarter of 2018, and, while substantial pain reduction associated with CINGAL was evident at each measurement point, we determined based on statistical analysis that it did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between CINGAL and the approved steroid component of CINGAL at the six-month time point. We initiated an additional three-month extended follow-up study in conjunction with the CINGAL 16-02 Study to investigate the efficacy of CINGAL over this longer period, and the first patients were enrolled in this follow-up study in the fourth quarter of 2017. Given the results of the CINGAL 16-02 Study, we continue to evaluate multiple strategies to optimize the potential U.S. regulatory pathway for CINGAL. After receiving the results from the three-month extended follow-up study, we intend to meet with FDA to discuss the totality of our clinical data for CINGAL and to identify and execute an optimal approach towards a potential future regulatory approval in the United States.

We have several research and development programs underway for new products, including for HYALOFAST (in the United States), an innovative product for cartilage tissue repair, and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is commercially available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption (“IDE”) for HYALOFAST to the FDA, which was approved in July 2015. We commenced patient enrollment in a clinical trial in December 2015, and we are advancing site initiations and patient enrollment activities. In the second quarter of 2016, a supplement to the HYALOFAST IDE was approved to expand the inclusion criteria for the clinical study. The purpose of this supplement is to allow us to increase enrollment rates with the ultimate goal of decreasing the time needed to complete the clinical trial. The voluntary recall described above does not impact the HYALOFAST clinical trial, as the product used in the clinical trial is not sourced from the affected production lots.

We are currently proceeding with other research and development programs, one of which utilizes our proprietary HA technology to treat pain associated with common repetitive overuse injuries, such as lateral epicondylitis, also known as tennis elbow. We submitted a CE Mark application for this treatment during the first quarter of 2016 and received a CE Mark for the treatment of pain associated with tennis elbow in December 2016. We expect to begin work on in a post-market clinical study in relation to the CE Mark for this product before the end of 2018. Outside of the United States, this product is marketed under the trade name ORTHOVISC-T. Additionally, in the second quarter of 2016, we submitted an IDE to the FDA to conduct a Phase III clinical trial for this treatment, which was approved by the FDA in June 2016. We also have other research and development programs underway focused on expanding the indications of our current products, including one program being conducted and funded by our U.S. MONOVISC distribution partner, DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics Inc., seeking to expand MONOVISC’s indication to include treatment of pain associated with osteoarthritis of the hip. In third quarter of 2017, we also submitted an application to the FDA for 510(k) clearance of an injectable HA-based bone repair treatment. The 510(k) clearance was received from the FDA in December 2017, and we expect to make this product commercially available during 2019. In addition to other early stage research and development initiatives we are currently undertaking, we are working to expand our regenerative medicine pipeline with a new product candidate in the form of an implant for rotator cuff repair utilizing our proprietary solid HA, for which we expect to have a developed prototype by the end of the year.

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. The agreement with the University of Massachusetts Amherst was extended in January 2018, and the next phase of the research will focus on optimizing the drug delivery system with the goal of advancing a novel therapeutic candidate into clinical trials to support regulatory submission. In January 2018, we entered into an agreement with the University of Liverpool to develop an injectable mesenchymal stem cell therapy for the treatment of age-related osteoarthritis with the goal of bringing a therapeutics candidate through clinical trials to market to meet an unmet therapeutic need.

Results of Operations

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

Three- and Six-Months Ended June 30, 2018 Compared to Three- and Six-Months Ended June 30, 2017

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	\$ Inc/(Dec)	% Inc/(Dec)	2018	2017	\$ Inc/(Dec)	% Inc/(Dec)
	(in thousands, except percentages)				(in thousands, except percentages)			
Product revenue	\$30,542	\$28,340	\$2,202	8 %	\$51,800	\$51,721	\$79	0 %
Licensing, milestone and contract revenue	6	5,122	(5,116)	*	12	5,127	(5,115)	*
Total revenue	30,548	33,462	(2,914)	(9 %)	51,812	56,848	(5,036)	(9 %)
Operating expenses:								
Cost of product revenue	8,152	6,315	1,837	29 %	15,996	12,398	3,598	29 %
Research and development	4,733	4,449	284	6 %	9,895	8,679	1,216	14 %
Selling, general & administrative	6,417	4,972	1,445	29 %	22,507	10,039	12,468	*
Total operating expenses	19,302	15,736	3,566	23 %	48,398	31,116	17,282	56 %
Income from operations	11,246	17,726	(6,480)	(37 %)	3,414	25,732	(22,318)	(87 %)
Interest and other income, net	290	16	274	*	385	74	311	*
Income before income taxes	11,536	17,742	(6,206)	(35 %)	3,799	25,806	(22,007)	(85 %)
Provision for income taxes	1,444	6,373	(4,929)	(77 %)	394	8,944	(8,550)	(96 %)
Net income	\$10,092	\$11,369	\$(1,277)	(11 %)	\$3,405	\$16,862	\$(13,457)	(80 %)
Product gross profit	\$22,390	\$22,025	\$365	2 %	\$35,804	\$39,323	\$(3,519)	(9 %)
Product gross margin	73 %	78 %			69 %	77 %		

* Percentage change has been omitted due to magnitude.

Product Revenue

Product revenue for the three-month period ended June 30, 2018 was \$30.5 million, an increase of 8% as compared to \$28.3 million for the three-month period ended June 30, 2017. Product revenue for the six-month period ended June 30, 2018 was \$51.8 million, an increase of \$0.1 million as compared to \$51.7 million for the six-month period ended June 30, 2017. For the six-month period ended June 30, 2018, the increase in product revenue growth was mainly driven by the increase in MONOVSC and CINGAL revenue. This increase was impacted by a decline in ORTHOVISC revenue, the effects of the previously described voluntary recall of certain production lots of our HYAFF-based products, and the timing of orders by our commercial partners.

The following tables present product revenue by product group:

Three Months Ended June 30,					
	2018	2017	\$	%	
			Inc/(Dec)	Inc/(Dec)	
	(in thousands, except percentages)				
Orthobiologics	\$26,192	\$24,468	\$ 1,724	7	%
Surgical	1,263	1,335	(72)	(5	%)
Dermal	623	453	170	38	%
Other	2,464	2,084	380	18	%
Total	\$30,542	\$28,340	\$ 2,202	8	%

Six Months Ended June 30,					
	2018	2017	\$	%	
			Inc/(Dec)	Inc/(Dec)	
	(in thousands, except percentages)				
Orthobiologics	\$45,681	\$44,695	\$ 986	2	%
Surgical	2,509	2,631	(122)	(5	%)
Dermal	83	878	(795)	(91	%)
Other	3,527	3,517	10	0	%
Total	\$51,800	\$51,721	\$ 79	0	%

Orthobiologics

Our orthobiologics franchise consists of our orthopedic pain management and regenerative therapies. Overall, sales increased 7% and 2% for the three- and six-month periods ended June 30, 2018, as compared to the same periods in 2017. The increase in the three-month period ended June 30, 2018 was primarily due to worldwide MONOVISC growth, and the overall increase in the six-month period ending June 30, 2018 was primarily due to worldwide MONOVISC and international CINGAL growth. In each period, the growth mentioned above was offset in part by declines in worldwide ORTHOVISC revenue, viscosupplementation product pricing declines in the U.S., and the timing of orders by our international commercial partners. The growth of MONOVISC revenue worldwide remains strong. We expect orthobiologics product revenue in 2018 to increase as compared to 2017, due to the growth of worldwide MONOVISC and international CINGAL revenue offset by a decline in ORTHOVISC revenue, U.S. viscosupplementation product pricing declines, and the effects of the previously described voluntary recall of certain production lots of our HYAFF-based products.

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 5% for the three- and six-month periods ended June 30, 2018 to \$1.3 million and \$2.5 million, respectively, as compared to the same periods in 2017. The decrease in surgical product revenue for the three-month period was primarily due to a decrease in sales to our worldwide ENT commercial partner, which was partially offset by an increase in sales of our surgical anti-adhesion products. We expect surgical product revenue to increase modestly in 2018 as compared to 2017 primarily due to increased worldwide sales of our surgical anti-adhesion products.

Dermal

Our dermal franchise consists of advanced wound care products, which are based on our HYAFF technology, and aesthetic dermal fillers. Our advanced wound care products treat complex skin wounds ranging from burns to diabetic ulcers, with HYALOMATRIX and HYALOFILL as the lead products. For the three- and six-month periods ended June 30, 2018, dermal product sales increased 38% and decreased 91%, respectively, as compared to the same periods in 2017. We expect dermal sales to decrease in 2018 as compared to 2017, due to the previously described voluntary recall of certain production lots of our HYAFF-based products.

Other

Other product revenue includes revenues from our ophthalmic and veterinary franchises. Other product revenue increased for the three-month period ended June 30, 2018 by \$0.4 million or 18%, and increased slightly for the six-month period ended June 30, 2018, both as compared to similar periods in 2017. We expect other revenue to increase in 2018 as compared to 2017, primarily driven by increases in ophthalmic revenue.

Product gross profit and margin

Product gross profit for the three- and six-month periods ended June 30, 2018 increased \$0.4 million and decreased \$3.5 million to \$22.4 and \$35.8 million, respectively, representing 73% and 69% of product revenue. Product gross profit for the three- and six-month periods ended June 30, 2017 was \$22.0 million and \$39.3 million, respectively, or 78% and 77% of product revenue for the periods. The decrease in product gross margin for the three-month period ended June 30, 2018, as compared to the same period in 2017, was due to a lower of cost or market adjustment on certain products, higher than planned production costs for our recently transferred HYAFF solid HA production, and revenue mix and pricing dynamics. The decrease in product gross margin for the six-month period ended June 30, 2018, as compared to the same period in 2017, was due to an increase in inventory reserves related to certain raw materials, inventory write-offs associated with the previously described voluntary recall of certain production lots of our HYAFF-based products, higher than planned production costs for our recently transferred HYAFF solid HA production, as well as revenue mix and pricing dynamics. We began remediation and mitigation plans during the first quarter of 2018 and currently expect to resolve the identified issues by the end of 2018. This current product gross margin may not be indicative of the rest of the year, and we expect to see continued improvement in product gross margin as we progress through 2018.

Research and development

Research and development expenses for the three- and six-month periods ended June 30, 2018 were \$4.7 million and \$9.9 million, representing 15% and 19% of total revenue for the respective periods, an increase of \$0.3 million and \$1.2 million, respectively as compared to the same periods in 2017. The increase in research and development expenses was primarily due to a higher level of regulatory and clinical activities, including with respect to our HYALOFAST and CINGAL Phase III clinical studies. Furthermore, we also increased our pre-clinical product development activities with respect to certain product candidates in our research and development pipeline. Research and development spending is expected to increase in 2018 and thereafter, as compared to 2017, as we further develop new products and line extensions and initiate new clinical trials based on our existing technology assets, as well as increase research and development activities for other products in the pipeline.

Selling, general and administrative

Selling, general and administrative (“SG&A”) expenses for the three- and six-month periods ended June 30, 2018 were \$6.4 million and \$22.5 million, representing 21% and 43% of total revenue for the period, an increase of \$1.4 million and \$12.5 million as compared to the same periods in 2017. The increase in SG&A expenses for the three-month period ending June 30, 2018 was primarily related to increased personnel, external professional fees, and marketing expenses. SG&A expenses increased for the six-month period ending June 30, 2018, as compared to prior period, primarily as a result of costs related to the retirement of our former Chief Executive Officer, certain accrued expenses related to the previously described voluntary recall of certain production lots of our HYAFF-based products, and increased personnel costs, external professional fees, and marketing expenses.

Income taxes

The provisions for income taxes were \$1.4 million and \$0.4 million for the three- and six- month periods ended June 30, 2018, based on effective tax rates of 12.5% and 10.4%, respectively. Provisions for income taxes were \$6.4 million and \$8.9 million for the three- and six- month periods ended June 30, 2017, based on effective tax rates of 35.9% and 34.7%, respectively. The net decrease in the effective tax rate for the three- and six- month periods ended June 30, 2018, as compared to the same periods in 2017, was primarily due to the reduction of Federal Corporate Income Tax rate as a result of the Tax Cuts and Jobs Act (“Tax Act”) tax reform legislation. This legislation makes significant changes to the U.S. tax law, including a reduction in the corporate tax rate from 35% to 21% starting in 2018. In addition, during the second quarter the Company realized windfall tax benefits related to exercises of employee equity awards resulting in a discrete period income tax benefit of \$1.3 million and a reduction in the effective tax rate of 11.3%.

Liquidity and Capital Resources

We require cash to fund our operating expenses and to make capital expenditures. We expect that our requirements for cash to fund these uses will increase as our operations expand. Historically we have generated positive cash flow from operations, which, together with our available cash, investments, and debt, have met our cash requirements. Cash, cash equivalents, and investments aggregated \$139.3 million and \$157.3 million, and working capital totaled \$178.5 million and \$193.3 million as of June 30, 2018, and December 31, 2017, respectively. In addition, we have \$50.0 million of available credit under our Senior Revolving Credit Facility as of June 30, 2018. We believe that we have adequate financial resources to support our business for at least the twelve months from the issuance date of our financial statements. As of June 30, 2018, we were in compliance with the terms of the Credit Agreement.

Cash provided by operating activities was \$14.1 million for the six-month period ended June 30, 2018, as compared to cash provided by operating activities of \$21.7 million for the same period in 2017. The decrease in cash provided by operations for the six-month period ended June 30, 2018, as compared to the same period in 2017, was primarily related to our higher operating expenses in manufacturing, research and development, and sales and marketing, prepayments of income taxes, and an increase in inventory on hand.

Cash provided by investing activities was \$7.5 million for the six-month period ended June 30, 2018, as compared to cash used in investing activities of \$8.4 million for the same period in 2017. The increase was due to maturities of investments and lower capital expenditures in comparison to 2017.

Cash used in financing activities was \$28.8 million for the six-month period ended June 30, 2018, as compared to cash provided by financing activities of \$0.2 million for the same period in 2017. The decrease in cash used in financing activities for the six-month period ended June 30, 2018, was primarily attributable to the utilization of \$30.0 million cash to repurchase outstanding common stock under the Fixed Dollar Accelerated Share Repurchase program.

Critical Accounting Policies and Estimates

There were no other significant changes in our critical accounting policies during the six months ended June 30, 2018 to augment the critical accounting policies 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, 2017 other than those described in the Notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, including the adoption of the FASB's Accounting Standards Codification Revenue from Contracts with Customers (ASC 606) effective January 1, 2018. As a result of our adoption of the new revenue recognition standard, we re-assessed the estimates, assumptions, and judgments that are most critical in our recognition of revenue and have revised our revenue recognition critical accounting policy. For information regarding the impact of recently adopted accounting standards, refer to Note 3.

There were no other significant changes in our critical accounting estimates during the six-month period ended June 30, 2018 to augment the critical accounting estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 other than those described in the Notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, including the estimated costs for the previously described voluntary recall of certain production lots of our HYAFF-based products.

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, 2017 and is updated in the Notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Contractual Obligations and Other Commercial Commitments

Our contractual obligations and other commercial commitments are summarized in the section captioned "Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Contractual Obligations and Other Commercial Commitments" in our Annual Report on Form 10-K for the

year ended December 31, 2017. Except for retirement and post-retirement consulting benefits of \$2.0 million we accrued on March 9, 2018 related to the retirement of our former Chief Executive Officer, we had no material changes outside the ordinary course to our contractual obligations reported in our 2017 Annual Report on Form 10-K during the six-month period ended June 30, 2018. For additional discussion, see Note 11 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

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, 2017. There have been no material changes in the first six months of 2018 to our market risks or to our management of such risks.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation
of
(a) 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 six-month period ended June 30, 2018 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting. In January 2018, we placed in service our new enterprise resource planning software. In this regard, we reviewed and modified our internal controls, as necessary.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are involved from time-to-time 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 occasional 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, 2017.

ITEM 1A. RISK FACTORS

Except as set forth below, 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, 2017. 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, 2017, 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.

Risks Related to Our Business and Industry

Failure to obtain, or any delay in obtaining, FDA or other U.S. and foreign governmental approvals for our products may have a material adverse effect on our business, financial condition and results of operations.

Several of our current products, and any future products we may develop, will require clinical trials to determine their safety and efficacy for United States and international marketing approval by regulatory bodies, including the FDA. Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance that the FDA will accept submissions related to our new products or the expansion of the indications of our current products, and, even if submissions are accepted, there can be no guarantee that the FDA will grant approval for our new products, including CINGAL, HYALOFAST, or other line extensions of our current products, or for the expansion of indications of our current products on a timely basis, if at all.

In the second quarter of 2018, we received and analyzed the results of our second Phase III clinical trial for CINGAL, our lead product candidate, and found that, while substantial pain reduction associated with CINGAL was evident at each measurement point, the data did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between CINGAL and the approved steroid component of CINGAL at the six-month time point. These results could have a substantial negative impact on the timeline for, and the cost associated with, CINGAL regulatory approval, if any, which could have a material adverse effect on our competitive position in the market in which we do business, and our overall business, financial condition, and results of operations.

In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local, and foreign regulations applicable to product approval, which may vary significantly across jurisdictions. Additional approval of existing products may be required when changes to such products may affect the safety and effectiveness, including for new indications for use, labeling changes, process or manufacturing changes, the use of a different facility to manufacture, process or package the device, and changes in performance or design specifications. Failure to obtain regulatory approvals of our products, including any changes to existing products, could have an adverse material impact on our business, financial condition, and results of operations.

Even if ultimately granted, FDA and international regulatory approvals may be subject to significant, unanticipated delays throughout the regulatory approval process. Internally, we make assumptions regarding product approval timelines, both in the United States and internationally, in our business planning, and any delay in approval could materially affect our competitive position in the relevant product market and our projections related to future business results. We were informed by our notified body that our CE Mark for MONOVISC was temporarily suspended as of March 27, 2018. On May 30, 2018, our notified body issued an updated CE Mark for MONOVISC.

We cannot be certain that product approvals, both in the United States and internationally, will not include significant limitations on the product indications and other claims sought for use, under which the products may be marketed. The relevant approval or clearance may also include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements. Any of these factors could significantly impact our competitive position in relation to such products and could have a negative impact on the sales of such products.

We are facing an unforeseen delay in implementing a direct sales model to commercialize our CINGAL product, as well as certain other future products, in the United States and we may face other unforeseen difficulties and delays in implementing this new model, which could affect our business and financial results.

We began the initial, pre-launch phases of implementing a direct sales model to commercialize and promote CINGAL in the United States, initially through a contract sales organization, with the ultimate goal of transitioning the direct sales function into our company as part of a broader buildout of our commercial capabilities. In the second quarter of 2018, we received and analyzed the results of our second Phase III clinical trial for CINGAL and found that, while substantial pain reduction associated with CINGAL was evident at each measurement point, the data did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between CINGAL and the approved steroid component of CINGAL at the six-month time point. Because these results could have a substantial negative impact on the timeline for and the cost associated with a potential CINGAL regulatory approval, if any, our overall business condition, financial results, and competitive position could be affected.

We also intended to use this direct sales model, at least in part, to potentially commercialize other products in the United States in the future. We believe that the combination of direct and distribution commercial models will maximize the revenue potential from our current and future product portfolio. We have delayed additional U.S. pre-launch activities for CINGAL as we evaluate its regulatory pathway in the United States, which will delay our implementation of a direct sales model for CINGAL and may delay implementation of the direct sales model for other products. These delays could reduce the revenue we generate from those products. If and when we proceed to implement a direct sales model for one or more products, we will need to allocate internal and external resources to manage the contract sales organization and the sales of the product. We cannot assure you that there will not be other unforeseen roadblocks or delays in finalizing the contracts related to, and implementing, the relationship with the contract sales organization, nor we can we assure you that we will not face setbacks in transitioning the direct sales function into our organization. Failure to implement our direct sales model in a timely fashion or to successfully manage the implementation or transition process could materially impact our competitive position, business, and financial results.

Once obtained, we cannot guarantee that FDA or international product approvals will not be withdrawn or that relevant agencies will not require other corrective action, and any withdrawal or corrective action could materially affect our business and financial results.

Once obtained, marketing approval can be withdrawn by the FDA or comparable foreign regulatory agencies for a number of reasons, including the failure to comply with ongoing regulatory requirements or the occurrence of unforeseen problems following initial approval. Regulatory authorities could also limit or prevent the manufacture or distribution of our products. We were informed by our notified body that our CE Mark for MONOVISC was temporarily suspended as of March 27, 2018. On May 30, 2018, our notified body issued an updated CE Mark for MONOVISC. Any regulatory limitations on the use of our products or any withdrawal or suspension of approval or rescission of approval by the FDA or a comparable foreign regulatory agency could have a material adverse effect on our business, financial condition, and results of operations.

Substantial competition could materially affect our financial performance.

We compete with many companies, including large pharmaceutical companies, specialized medical products companies, and healthcare companies. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations, and more experience in the regulatory process than we do. We also compete with academic institutions, government agencies, and other research organizations that may be involved in research, development, and commercialization of products similar to our own. Because a number of companies are developing or have developed HA products for similar applications and have received FDA approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory approval is not obtained prior to our competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. For example, we are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval, or have commenced human clinical studies, either in the United States or in certain foreign countries. There exist major competing products for the use of HA in ophthalmic surgery. In addition, certain HA products made by our competitors for the treatment of osteoarthritis in the knee received FDA approval before ours and have been marketed in the United States since 1997, as well as select markets in Canada, Europe, and other countries. There can be no assurance that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition, and results of operations.

In the second quarter of 2018, we received and analyzed the results of our second Phase III clinical trial for CINGAL and found that, while substantial pain reduction associated with CINGAL was evident at each measurement point, the data did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between CINGAL and the approved steroid component of CINGAL at the six-month time point. These results could have a substantial negative impact on the timeline for CINGAL's commercial launch in the United States, if regulatory approval is ultimately achieved, which could negatively impact our competitive position and have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Ownership of Our Common Stock

Our stock price may be highly volatile, and we cannot assure you that market making in our common stock will continue.

The market price of shares of our common stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, government regulation and approvals, developments in patent or other proprietary rights, public concern as to the safety of products developed by us, and general market conditions may have a significant effect on the market price of our common stock. The trading price of our common stock could be subject to wide fluctuations in response to quarter-to-quarter variations in our operating results, material announcements by us or our competitors, governmental regulatory action, conditions in the health care industry generally or in the medical products industry specifically, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical products companies and which often have been unrelated to the operating performance of such companies. Our operating results in future quarters may be below the expectations of equity research analysts and investors. In such an event, the price of our common stock would likely decline, perhaps substantially.

In the second quarter of 2018, we analyzed the results of our second Phase III clinical trial for CINGAL and found that, while substantial pain reduction associated with CINGAL was evident at each measurement point, the data did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between CINGAL and the approved steroid component of CINGAL at the six-month time point. We publicly announced these results on June 19, 2018, after which we observed a substantial decline in the price of our common stock. These Phase III clinical results could aggravate the volatility of our stock in the short term, and we cannot guarantee that we will not experience wide stock price fluctuations in the future.

Our charter documents contain anti-takeover provisions that may prevent or delay an acquisition of our company.

At our Annual Meeting of Stockholder on May 31, 2018, our stockholders ratified the reincorporation of our company from the Commonwealth of Massachusetts to the State of Delaware. We became a Delaware corporation with a new Certificate of Incorporation and new Bylaws, effective as of June 6, 2018. Our new charter documents continue to contain anti-takeover provisions that could prevent or delay an acquisition of our company. The provisions include, among others, a classified board of directors, advance notice to the board of stockholder proposals, limitations on the ability of stockholders to remove directors and to call stockholder meetings, and a provision that allows vacancies on the Board of Directors to be filled by vote of a majority of the remaining directors. We are also subject to Section 203 of the Delaware General Corporate Law which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any “interested stockholder” for a period of three years following the date that such stockholder becomes an interested stockholder. Those provisions could have the effect of discouraging a third party from pursuing a non-negotiated takeover of our company at a price considered attractive by

many stockholders and could have the effect of preventing or delaying a potential acquirer from acquiring control of our company.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

Under our equity compensation plans, and subject to the specific approval of the Compensation Committee of our Board of Directors, grantees have the option of electing to satisfy tax withholding obligations at the time of vesting or exercise by allowing us to withhold shares of stock otherwise issuable to the grantee. During the three-month period ended June 30, 2018, there were no shares withheld to satisfy grantee tax withholding obligations on restricted stock award vesting events.

Following is a summary of stock repurchases for the three-month period ended June 30, 2018 (in thousands, except share data):

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, 2018	-	-	-	\$ -
May 1 to 31, 2018	434,678	-	434,678	\$ 12,000
June 1 to 30, 2018	-	-	-	\$ 12,000
Total	434,678	-	434,678	

On May 24, 2018, we entered into a previously-announced accelerated stock repurchase agreement (the “ASR Agreement”) to repurchase an aggregate of \$30.0 million of our common stock. During the second quarter of 2018, 434,678 shares were delivered to us under the ASR Agreement, constituting the initial delivery of shares under the ASR Agreement. On July 16, 2018, pursuant to the terms of the ASR Agreement, Morgan Stanley accelerated the final settlement date from December 2018, and the final number of shares and the average purchase price was (1) determined. Based on the volume-weighted average price from the effective date of the ASR Agreement through July 16, 2018, less the applicable contractual discount, Morgan Stanley delivered 372,140 additional shares to us on July 19, 2018. In total, 806,818 shares were repurchased under the ASR Agreement at an average repurchase price of approximately \$37.18. All shares were repurchased in accordance with the publicly announced program. Final settlement occurred on July 16, 2018, and we will not make further purchases under the program.

ITEM 6. EXHIBITS

Exhibit No. Description

- 2.1 Plan of Domestication of Anika Therapeutics, Inc., as adopted by Anika Therapeutics, Inc. on March 23, 2018 and approved by the stockholders of Anika Therapeutics, Inc. on May 31, 2018.
- *10.1 Fixed Dollar Accelerated Share Repurchase Transaction Confirmation entered into as of May 24, 2018 by and between Morgan Stanley & Co. LLC and Anika Therapeutics, Inc.
- (31) Rule 13a-14(a)/15d-14(a) Certifications
- *31.1 Certification of Joseph G. Darling, 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 Joseph G. Darling, and Sylvia Cheung, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (101) XBRL
- *101 The following materials from Anika Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, as filed with the SEC on July 31, 2018, formatted in XBRL (eXtensible Business Reporting Language), as follows:
- i. Condensed Consolidated Balance Sheets as of June 30, 2018 (unaudited) and December 31, 2017 (unaudited)
 - ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Six Months Ended June 30, 2018 and June 30, 2017 (unaudited)
 - iii. Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2018 and June 30, 2017 (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: July 31, 2018 By: /s/ SYLVIA CHEUNG
Sylvia Cheung
Chief Financial Officer
(Authorized Officer and Principal Financial Officer)