Anika Therapeutics, Inc.
Form 10-Q
May 10, 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 March 31, 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)

Massachusetts	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
32 Wiggins Avenue, Bedford, Massachusetts	**01730**
(Address of Principal Executive Offices)	(Zip Code)

(781) 457-9000

(Registrant's Telephone Number, Including Area Code)

N/A

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

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

Indicate by check mark whether the registrant has submitted electronically 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 x No o

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

Large accelerated filer	Accelerated filer	Non-accelerated filer (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 May 3, 2018, there were 14,745,152 outstanding shares of Common Stock, par value $.01 per share.

ANIKA THERAPEUTICS, INC.

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References in this Quarterly Report on Form 10-Q to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands, except per share data)

(unaudited)

ASSETS	March 31, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	$141,797	$133,256
Investments	21,250	24,000
Accounts receivable, net of reserves of $2,180 and $1,914 at March 31, 2018 and December 31, 2017, respectively	18,289	23,825
Inventories, net	22,770	22,035
Prepaid expenses and other current assets	4,081	3,211
Total current assets	208,187	206,327
Property and equipment, net	55,772	56,183
Other long-term assets	1,247	1,254
Intangible assets, net	10,678	10,635
Goodwill	8,452	8,218
Total assets	$284,336	$282,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$6,159	$6,747
Accrued expenses and other current liabilities	7,963	6,326
Total current liabilities	14,122	13,073
Other long-term liabilities	1,150	660
Deferred tax liability	5,298	5,393
Commitments and contingencies (Note 12)		

Stockholders' equity:		
Preferred stock, $.01 par value; 1,250 shares authorized, no shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Common stock, $.01 par value; 60,000 shares authorized, 14,745 and 14,688 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	147	147
Additional paid-in-capital	74,958	68,617
Accumulated other comprehensive loss	(4,164)	(4,784)
Retained earnings	192,825	199,511
Total stockholders' equity	263,766	263,491
Total liabilities and stockholders' equity	$284,336	$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 (Loss)

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Product revenue	$21,258	$23,381
Licensing, milestone and contract revenue	6	5
Total revenue	21,264	23,386
Operating expenses:		
Cost of product revenue	7,845	6,083
Research & development	5,161	4,230
Selling, general & administrative	16,090	5,067
Total operating expenses	29,096	15,380
Income (loss) from operations	(7,832)	8,006
Interest and other income, net	95	58
Income (loss) before income taxes	(7,737)	8,064
Provision for (benefit from) income taxes	(1,051)	2,571
Net income (loss)	$(6,686)	$5,493
Basic net income (loss) per share:		
Net income (loss)	$(0.46)	$0.38
Basic weighted average common shares outstanding	14,679	14,576
Diluted net income (loss) per share:		
Net income (loss)	$(0.46)	$0.37
Diluted weighted average common shares outstanding	14,679	15,043
Net income (loss)	$(6,686)	$5,493
Foreign currency translation adjustment	620	292
Comprehensive income (loss)	$(6,066)	$5,785

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)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	$ (6,686)	$ 5,493
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	1,473	1,014
Loss on disposal of fixed assets	142	-
Stock-based compensation expense	7,565	1,182
Deferred income taxes	(75)	385
Provision for inventory	3,246	264
Changes in operating assets and liabilities:		
Accounts receivable	5,730	6,601
Inventories	(3,924)	(431)
Prepaid expenses, other current and long-term assets	509	744
Accounts payable	(180)	2,020
Accrued expenses, other current and long-term liabilities	3,270	(1,807)
Income taxes	(1,478)	(5)
Net cash provided by operating activities	9,592	15,460
Cash flows from investing activities:		
Proceeds from maturity of investments	15,250	12,500
Purchase of investments	(12,500)	(11,250)
Purchase of property and equipment	(2,543)	(1,675)
Net cash provided by (used in) investing activities	207	(425)
Cash flows from financing activities:		
Cash paid for tax withheld on vested restricted stock awards	(1,735)	-
Proceeds from exercise of equity awards	512	41
Net cash (used in) provided by financing activities	(1,223)	41
Exchange rate impact on cash	(35)	31
Increase in cash and cash equivalents	8,541	15,107
Cash and cash equivalents at beginning of period	133,256	104,261
Cash and cash equivalents at end of period	$ 141,797	$ 119,368
Supplemental disclosure of cash flow information:		

Non-cash Investing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 207	$ 2,081

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 the Company's proprietary Hyaluronic Acid ("HA") technology. The Company's orthopedic medicine portfolio includes ORTHOVISC, MONOVISC, and CINGAL, which alleviate pain and restore joint function by replenishing depleted HA, and HYALOFAST, a solid HA-based scaffold to aid cartilage repair and regeneration.

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

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and in accordance with accounting principles generally accepted in the United States ("US GAAP"). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with US GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. The December 31, 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 March 31, 2018, the results of its operations for the three-month periods ended March 31, 2018 and 2017, and cash flows for the three-month periods ended March 31,

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-month period ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which requires an entity to recognize revenue for the transfer of goods or services equal to the amount that it expects to be entitled in exchange for those goods or services. ASU 2014-09 supersedes most previous revenue recognition guidance and is effective for interim and annual reporting periods beginning within 2018. The Company adopted the new guidance as of January 1, 2018 using the modified retrospective adoption method. See Note 3 for further details.

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

3. Revenue

The Company adopted the guidance in the FASB's Accounting Standards Codification (ASC) Revenue from Contracts with Customers (ASC 606) using the modified retrospective method effective January 1, 2018. The adoption of ASC 606 was applied to all contracts not completed as of the date of adoption. The adoption did not have a material impact on the amount and timing of revenue recognized in the condensed consolidated financial statements.

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 limited number of distributors. The Company's distributors subsequently resell the products to their customers, which includes 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. 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 contractually stated contract terms. The Company's contracts with customers do not provide a right of return, unless certain product quality standards are not met.

To identify variable considerations and determine the transaction price, the Company has reviewed its standard 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 deferral may be required.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or after performance, resulting in a significant financing component. Applying the practical expedient in paragraph ASC 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less.

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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 March 31, 2018, deferred revenue was immaterial.

Generally, the 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. Value add and other taxes collected by the Company concurrently with revenue-producing activities are excluded from revenue. 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 these license arrangements. 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 76% of total Company revenues in the first quarter of 2018. The Company has agreements with other customers that may include the delivery of a license and supply of product. The adoption of ASC 606 did not impact the accounting for these agreements.

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

Variable consideration is included in the transaction price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring 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). 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. Revenue from sales-based royalties is included in product revenues as discussed above.

As a result of applying the modified retrospective method to adopt the new revenue guidance, there was no cumulative effect to balance sheet accounts as of the adoption date.

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 Ended March 31,	
	2018	2017
Orthobiologics	$ 19,489	$ 20,227
Surgical	1,245	1,296
Dermal	(539)	425
Other	1,063	1,433
Product Revenue	$ 21,258	$ 23,381

Total revenue by geographic location and as a percentage of overall total revenue for the three-month periods ended March 31, 2018 and 2017 are as follows:

	Three Months Ended March 31,					
	2018			2017		
	Total Revenue	Percentage of Revenue		Total Revenue	Percentage of Revenue	
Geographic Location:						
United States	$16,910	80	%	$18,930	81	%
Europe	2,391	11	%	2,829	12	%
Other	1,963	9	%	1,627	7	%
Total Revenue	$21,264	100	%	$23,386	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. 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 and is recorded in accrued expenses and $0.2 million which is recorded against outstanding receivables. 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 (loss), net of related income taxes. The Company held bank certificates of deposit of $21.3 million and $24.0 million at March 31, 2018 and December 31, 2017, respectively. There were no unrealized gains or losses on the Company’s available-for-sale securities at March 31, 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:

		Fair Value Measurements at Reporting Date Using		
	March 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$6,504	$ 6,504	$ -	$ -
Bank certificates of deposit	2,750	-	2,750	-
Total cash equivalents	$9,254	$ 6,504	$ 2,750	$ -
Investments:				
Bank certificates of deposit	$21,250	$ -	$ 21,250	$ -

		Fair Value Measurements at Reporting Date Using		
	December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 5,893	$ 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 three-month periods ended March 31, 2018 and 2017 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2018	2017
Risk free interest rate	2.15% - 2 .37%	1.70% - 1.78%
Expected volatility	38.74% - 40.81%	43.47% - 44.30%
Expected life (years)	4.5	4.0
Expected dividend yield	0.00%	0.00%

The Company recorded $7.6 million and $1.2 million of stock-based compensation expense for equity compensation awards for the three-month periods ended March 31, 2018 and 2017, respectively. 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 Ended March 31,	
	2018	2017
Cost of product revenue	$ (216)	$ 97
Research & development	210	10
Selling, general & administrative	7,571	1,075
Total stock-based compensation expense	$ 7,565	$ 1,182

The decrease in stock-based compensation expense within the cost of product revenue line item during the three months ended March 31, 2018 is due to forfeitures associated with unvested stock option awards from the resignation of a former executive.

During the three-month periods ended March 31, 2018 and 2017, the Company granted stock option awards to employees of 192,300 and 392,005 shares, respectively, which become exercisable or vest ratably over four-year and three-year periods, respectively. For the three-month period ended March 31, 2018, the Company granted 64,578 shares subject to RSAs. In addition, the Company executed its annual grant of RSUs to non-employee directors, and 8,130 and 9,970 RSUs were granted to non-employee directors in January 2018 and 2017, respectively, 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 (Loss) Per Share (“EPS”)

Basic EPS is calculated by dividing net income (loss) 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 (loss) 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 (loss) per share (in thousands):

	Three Months Ended March 31,	
	2018	2017

Shares used in the calculation of basic earnings (loss) per share	14,679	14,576
Effect of dilutive securities:		
Stock options, SARs, RSAs and RSUs	-	467
Diluted shares used in the calculation of earnings (loss) per share	14,679	15,043

For the three months ended March 31, 2018, the net loss available to common shareholders is divided by the weighted average number of common shares outstanding during the period to calculate basic earnings per share. The assumed exercise of stock options at March 31, 2018 would have been anti-dilutive. Stock options to purchase 1.0 million shares and 0.6 million shares for the three-month periods ended March 31, 2018 and 2017, were excluded from the computation of diluted EPS as their effect would have been anti-dilutive.

8. Inventories

Inventories consist of the following:

	March 31, 2018	December 31, 2017
Raw materials	$10,062	$11,296
Work-in-process	5,899	6,062
Finished goods	6,809	4,677
Total	$22,770	$22,035

As a result of the voluntary recall more fully described in Note 3, the Company recorded inventory reserves of $0.6 million for non-saleable inventory. In addition, the Company recorded an inventory reserve of $1.7 million for HA raw materials.

9. Intangible Assets

Intangible assets as of March 31, 2018 and December 31, 2017 consist of the following:

	March 31, 2018				December 31, 2017				
	Gross Value	Accumulated Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Accumulated Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Useful Life
Developed technology	$17,100	$(2,358)	$(7,970)	$6,772	$(2,550)	$(7,723)	$6,827	15
In-process research & development	4,406	(916)		3,490	(1,015)	-	3,391	Indefinite
Distributor relationships	4,700	(415)	(4,285)	-	(415)	(4,285)	-	5
Patents	1,000	(140)	(444)	416	(152)	(431)	417	16
Elevess trade name	1,000	-	(1,000)	-	-	(1,000)	-	9
Total	$28,206	$(3,829)	$(13,699)	$10,678	$(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 March 31, 2018 and 2017, respectively.

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 March 31, 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:

	March 31, 2018
Balance at January 1, 2018	$8,218
Effect of foreign currency adjustments	234
Balance at March 31, 2018	$8,452

11. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2018	December 31, 2017
Compensation and related expenses	$2,844	$ 2,893
Clinical trial costs	2,402	2,318
Revenue reserves and accrued expenses related to product recall	1,381	-
Research grants	431	419
Professional fees	676	448
Other	229	248
Total	$7,963	$ 6,326

Included in Compensation and related expenses as of March 31, 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 aggregate severance 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.

Revenue reserves and accrued expenses 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 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 at March 31, 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

Benefits from and (provisions for) income taxes were $1.1 million and ($2.6) million for the three-month periods ended March 31, 2018 and 2017, respectively, based on effective tax rates of 13.6% and (31.9%). The net decrease in the effective tax rate for the three-month period ended March 31, 2018, as compared to the same period in 2017, was primarily due to 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. The tax benefit for the quarter was lower than the statutory rate predominately due to limitations on the deductibility of executive compensation for accelerated stock vesting upon the retirement of our former Chief Executive Officer on March 9, 2018.

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

In connection with the preparation of the financial statements, the Company performed an analysis to ascertain if it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its net operating loss carry-forward. The Company has concluded that the positive evidence outweighs the negative evidence and, thus, that the deferred tax assets not otherwise subject to a valuation allowance are realizable on a “more likely than not” basis. As such, the Company did not record a valuation allowance at March 31, 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 devices 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 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS 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 future prospects and make informed investment decisions. Forward-looking statements are subject to risks and uncertainties, many of which are outside our control, which could cause actual results to differ materially from these statements. Therefore, you should not rely on any of these forward-looking statements. Forward-looking statements can be identified by such words as "will," "likely," "may," "believe," "expect," "anticipate," "intend," "seek," "designed," "develop," "would," "future," "can," "could," and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, operations, costs, plans, and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements regarding expected future operating results, expectations regarding the timing and receipt of regulatory results, anticipated levels of capital expenditures, and expectations of the effect on our financial condition of claims, litigation, and governmental and regulatory proceedings.

Please also refer to those factors described in Part II, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 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. In 2015, we made the strategic decision to commercialize our next generation viscosupplementation product, CINGAL, in the United States ourselves, initially through the engagement of a contract sales organization. Ultimately, we intend to transition the direct sales function into our company as part of a broader buildout of our commercial capabilities. We have made substantial progress on this initiative, and we are currently in process of optimizing and finalizing our plans for the commercial launch of CINGAL. 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. We have been in regular communication with the notified body, and we are working expeditiously towards an appropriate resolution. This matter did not impact our revenue for the quarter ended March 31, 2018. Based on the facts currently known to us, we believe the suspension can be resolved during the second quarter of 2018 and therefore will not impact our results in any future periods.

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 is no indication of any safety or efficacy issue related to the products at this time, we remain committed to the highest standards of quality and are removing the products from the field as a precautionary measure. The overall revenue impact of this voluntary recall was $1.1 million, of which $0.9 million relates to prior periods. As a result of the voluntary recall, we had an inventory charge of $0.6 million for the related non-saleable inventory at March 31, 2018. In addition, we accrued $0.4 million for future expenses associated with the administration of the voluntary recall. 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 is CINGAL, which is composed of our proprietary cross-linked HA material combined with an approved steroid and is designed to provide

both short- and long-term pain relief to patients. We completed an initial CINGAL Phase III clinical trial, including the associated statistical analysis for 368 enrolled patients, during the fourth quarter of 2014 with data indicating that the product met all primary and secondary endpoints relative to placebo set forth for the trial. During the first half of 2015, we completed a CINGAL retreatment study with 242 patients who had participated in the Phase III clinical trial and reported safety data related to the retreatment study. This initial Phase III clinical trial and the associated retreatment study supported the Health Canada and CE Mark approval of the product, and the commercial launch of the product in both Canada and the European Union occurred in the second quarter of 2016. In the United States, after discussions with the U.S. Food and Drug Administration ("FDA") related to the regulatory pathway for CINGAL, we conducted a formal meeting with the FDA's Office of Combination Products ("OCP") to present and discuss our data in September 2015, and we submitted a formal request for designation with OCP a month later. In its response to our formal request for designation, OCP assigned the product to the FDA's Center for Drug Evaluation and Research ("CDER") as the lead agency center for premarket review and regulation. Since then, we have been in ongoing discussions with CDER to understand the requirements for submitting a New Drug Application ("NDA") for CINGAL. We held a meeting with CDER in September 2016 to align on an approval framework and on submission requirements for this NDA for CINGAL, including the execution of an additional Phase III clinical trial to supplement our existing CINGAL pivotal study data. We submitted an Investigational New Drug Application ("IND") in late 2016, and discussions with CDER indicated that they do not have objections to our clinical protocol design. As a result, we commenced work on this second Phase III clinical trial in the first quarter of 2017, and the first patient was treated in the second quarter of 2017. Enrollment of the 576 patients in this second Phase III clinical trial was completed during October 2017. We completed the six-month follow-up for this Phase III clinical trial in April 2018. We expect to submit our NDA to FDA as expeditiously as possible. We have also initiated an additional three-month extended follow-up study in conjunction with the second Phase III clinical trial 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. This extended follow-up study will not impact the timeline for submission of the NDA for CINGAL following the completion of the second Phase III clinical trial.

We have several research and development programs underway for new products, including for HYALOFAST (in the United States), an innovative product for cartilage tissue repair, and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is commercially available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption ("IDE") for HYALOFAST to the FDA, which was approved in July 2015. We commenced patient enrollment in a clinical trial in December 2015, and we are advancing site initiations and patient enrollment activities. In the second quarter of 2016, a supplement to the HYALOFAST IDE was approved to expand the inclusion criteria for the clinical study. The purpose of this supplement is to allow us to increase enrollment rates with the ultimate goal of decreasing the time needed to complete the clinical trial. 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 will be 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. 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, which is progressing towards the conceptual phase of prototype development.

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. We also recently 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

Three Months Ended March 31, 2018 compared to Three Months Ended March 31, 2017:

	Three Months Ended March 31,			
	2018	2017	$ Inc/(Dec)	% Inc/(Dec)
	(in thousands, except percentages)			
Product revenue	$21,258	$23,381	$(2,123)	(9%)
Licensing, milestone and contract revenue	6	5	1	20%
Total revenue	21,264	23,386	(2,122)	(9%)
Operating expenses:				
Cost of product revenue	7,845	6,083	1,762	29%
Research & development	5,161	4,230	931	22%
Selling, general & administrative	16,090	5,067	11,023	218%
Total operating expenses	29,096	15,380	13,716	89%
Income (loss) from operations	(7,832)	8,006	(15,838)	(198%)
Interest and other income, net	95	58	37	64%
Income (loss) before income taxes	(7,737)	8,064	(15,801)	(196%)
Provision for (benefit from) income taxes	(1,051)	2,571	(3,622)	(141%)
Net income (loss)	$(6,686)	$5,493	$(12,179)	(222%)
Product gross profit	$13,413	$17,298	$(3,885)	(22%)
Product gross margin	63%	74%		

Product Revenue

Product revenue for the three-month period ended March 31, 2018 was $21.3 million, a decrease of 9% as compared to $23.4 million for the three-month period ended March 31, 2017. For the three-month period ended March 31, 2018, the decrease in product revenue was due to 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 for the three-month periods ended March 31, 2018 and 2017:

	Three Months Ended March 31,			
	2018	2017	$ Inc/(Dec)	% Inc/(Dec)
	(in thousands, except percentages)			
Orthobiologics	$19,489	$20,227	$ (738)	(4 %)
Surgical	1,245	1,296	(51)	(4 %)
Dermal	(539)	425	(964)	(227 %)
Other	1,063	1,433	(370)	(26 %)
Total	$21,258	$23,381	$ (2,123)	(9 %)

Orthobiologics

Our orthobiologics franchise consists of our orthopedic pain management and regenerative therapies. Overall, sales decreased 4% for the three-month period ended March 31, 2018, as compared to the same period in 2017. The overall decline in the three-month period ending March 31, 2018 was primarily due to decline in worldwide ORTHOVISC revenue, U.S. pricing declines, and the timing of orders by our international commercial partners. This decline during the first quarter was partially off-set by a 29% increase in worldwide MONOVISC revenue. This is indicative of MONOVISC’s strong worldwide growth trajectory, and results, in part, from the market trend to shift from multi-injection to single-injection products. Continued strong international demand for CINGAL also contributed to the growth of orthobiologics revenue during the period. We expect orthobiologics product revenue in 2018 to remain at a similar level as compared to 2017, due to the decline in ORTHOVISC revenue offset by the growth of worldwide MONOVISC and international CINGAL revenue.

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 4% to $1.2 million during the three-month period ended March 31, 2018, as compared to the same period 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-month period ended March 31, 2018, dermal product sales decreased 227%, as compared to the same period in 2017, and 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 decreased by $0.4 million or 26% as compared to the same period in 2017, primarily due to lower than expected sales of our veterinary product, HYVISC. 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-month period ended March 31, 2018 decreased $3.9 million to $13.4 million, representing 63% of product revenue. Product gross profit for the three months ended March 31, 2017 was $17.3 million, or 74% of product revenue for the period. The decrease in product gross margin for the three-month period ended March 31, 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 the year. This

current product gross margin may not be indicative of the rest of the year, and we expect to see improvement in product gross margin as we progress through 2018.

Research and development

Research and development expenses for the three-month period ended March 31, 2018 were $5.2 million, or 24% of total revenue for the period, an increase of $0.9 million, as compared to the same period 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, including CINGAL and HYALOFAST, 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-month period ended March 31, 2018 were $16.1 million, representing 76% of total revenue for the period, an increase of $11.0 million as compared to the same period in 2017. SG&A expenses increased for the three-month period ending March 31, 2018, and we expect that they will continue to increase in 2018 as compared to prior periods, primarily as a result of costs related to the retirement of our former Chief Executive Officer, prelaunch activities required to support the commercialization of CINGAL in the United States, certain accrued expenses related to the previously described voluntary recall of certain production lots of our HYAFF-based products, and increased personnel costs.

Income taxes

Benefits from and (provisions for) income taxes were $1.1 million and ($2.6) million for the three-month periods ended March 31, 2018 and 2017, respectively, based on effective tax rates of 13.6% and (31.9%). The net decrease in the effective tax rate for the three-month period ended March 31, 2018, as compared to the same period in 2017, was primarily due to 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. The tax benefit for the quarter was lower than the statutory rate predominately due to limitations on the deductibility of executive compensation for accelerated stock vesting upon the retirement of our former Chief Executive Officer on March 9, 2018.

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 $163.0 million and $157.3 million, and working capital totaled $194.1 million and $193.3 million at March 31, 2018, and December 31, 2017, respectively. In addition, we have $50.0 million of available credit under our Senior Revolving Credit Facility as of March 31, 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 March 31, 2018, we were in compliance with the terms of the Credit Agreement.

Cash provided by operating activities was $9.6 million for the three-month period ended March 31, 2018, as compared to cash provided by operating activities of $15.5 million for the same period in 2017. The decrease in cash provided by operations for the three-month period ended March 31, 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 used in investing activities was $0.2 million for the three-month period ended March 31, 2018, as compared to cash used in investing activities of $0.4 million for the same period in 2017. The increase was due to the increased maturities of investments in comparison to 2017.

Cash used by financing activities was $1.2 million for the three-month period ended March 31, 2018, as compared to cash provided by financing activities of $41 thousand for the same period in 2017. The increase in cash used in financing activities for the three-month period ended March 31, 2018, was primarily attributable to utilization of cash for employee tax withholding in exchange for shares surrendered by equity award holders.

Critical Accounting Policies and Estimates

There were no other significant changes in our critical accounting policies during the three months ended March 31, 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 three months ended March 31, 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 three months ended March 31, 2018. For additional discussion, see Note 12 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 three months of 2018 to our market risks or to our management of such risks.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

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

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the three-month period ended March 31, 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 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 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 were informed by our notified body that our CE Mark for MONOVISC was temporarily suspended as of March 27, 2018. While we expect that this will not materially impact our business, there is no guarantee that our notified body will work with us to reinstate our CE Mark in a timely manner or at all. If this were to occur, our competitive position and distributor relationships could be affected, which could have an adverse material impact on our business, financial condition, and results of operations.

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. 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.

We were informed by our notified body that our CE Mark for MONOVISC was temporarily suspended as of March 27, 2018. While we expect that this will not materially impact our business, there is no guarantee that our notified body will work with us to reinstate our CE Mark in a timely manner or at all. If this were to occur, our competitive position and distributor relationships could be affected, which could have an adverse material impact on our business, financial condition, and results of operations.

Additionally, on May 2, 2018, we announced a voluntary recall of certain production lots of our HYAFF-based products, including HYALOFAST, HYALOGRAFT C, and HYALOMATRIX. 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. The ultimate financial impact with respect to this matter will depend on many factors that are difficult to predict with the information available to date, and it could vary materially based on the impact of this matter on our distributor relationships, the amount of time required to resume the production and shipping of these products, and any changes to the competitive position of the products in the markets in which they are distributed.

Our operations and products are subject to extensive regulation, compliance with which is costly and time consuming, and our failure to comply may result in substantial penalties, including recalls of our products.

The FDA and foreign regulatory bodies impose extensive regulations applicable to our operations and products, including regulations governing product standards, packing requirements, labeling requirements, quality system and manufacturing requirements, import restrictions, tariff regulations, duties, and tax requirements. We cannot assure you that we will be able to achieve and maintain compliance required for FDA, CE marking, or other foreign regulatory approvals for any or all of our operations and products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements.

Failure to comply with applicable regulatory requirements could result in substantial penalties, including warning letters, fines, injunctions, civil penalties, seizure of products, total or partial suspension of production, refusal to grant pre-market clearance or pre-market approval for devices or drugs, withdrawal of approvals, and criminal prosecution. Additionally, regulatory authorities have the power to require the recall of our products. It also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per regulatory requirements of one or several of our products, as was the case with respect to the recall of HYALOFAST, and HYALOGRAFT C, and HYALOMATRIX. which was announced on May 2, 2018. The imposition of any of the foregoing penalties, whether voluntarily or involuntary, could have a material negative impact on our business, financial condition, and results of operations.

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 months ended March 31, 2018, we withheld 32,451 shares to satisfy grantee tax withholding obligations on restricted stock award vesting events. There is no publicly announced open market purchase program at this time.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Plans or Programs
March 2018	32,451	$ 53.49	-	$ -
Total	32,451	$ 53.49	-	$ -

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1	Consulting Agreement between Anika Therapeutics, Inc. and Charles H. Sherwood, Ph.D. dated March 8, 2018, incorporated herein by reference to Exhibit 10.3 to Form 8-K, filed with the SEC on March 8, 2018.
10.2	Amendment No. 1 dated March 8, 2018 to Employment Agreement dated July 27, 2017 by and between Anika Therapeutics, Inc. and Joseph G. Darling, incorporated herein by reference to Exhibit 10.4 to Form 8-K, filed with the SEC on March 8, 2018.
(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 March 31, 2018, as filed with the SEC on May 10, 2018, formatted in XBRL (eXtensible Business Reporting Language), as follows: i. Condensed Consolidated Balance Sheets as of March 31, 2018 (unaudited) and December 31, 2017 (unaudited) ii. Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the Three Months Ended March 31, 2018 and March 31, 2017 (unaudited) iii. Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2018 and March 31, 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: May 10, 2018 By: /s/ SYLVIA CHEUNG
Sylvia Cheung
Chief Financial Officer
(Authorized Officer and Principal Financial Officer)