

Anika Therapeutics, Inc.
Form 10-Q
October 26, 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 September 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)

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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 every Interactive Data File required to be submitted 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 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.

| | | | | | |
|-------------------------|-------------------|-----------------------|--|-------------------|-----------------|
| | | | | Smaller reporting | Emerging growth |
| Large accelerated filer | Accelerated filer | Non-accelerated filer | | company | company |

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

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As of October 18, 2018, there were 14,211,457 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.

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)**

| | September 30, 2018 | December 31, 2017 |
|---|--------------------------|-------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$81,825 | \$133,256 |
| Investments | 67,186 | 24,000 |
| Accounts receivable, net of reserves of \$1,771 and \$1,914 at September 30, 2018 and December 31, 2017, respectively | 20,771 | 23,825 |
| Inventories, net | 23,828 | 22,035 |
| Prepaid expenses and other current assets | 1,981 | 3,211 |
| Total current assets | 195,591 | 206,327 |
| Property and equipment, net | 55,041 | 56,183 |
| Other long-term assets | 1,109 | 1,254 |
| Intangible assets, net | 9,564 | 10,635 |
| Goodwill | 7,959 | 8,218 |
| Total assets | \$269,264 | \$282,617 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$2,462 | \$6,747 |
| Accrued expenses and other current liabilities | 6,843 | 6,326 |
| Total current liabilities | 9,305 | 13,073 |
| Other long-term liabilities | 574 | 660 |
| Deferred tax liability | 4,120 | 5,393 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Preferred stock, \$.01 par value; 1,250 shares authorized, no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | - | - |
| Common stock, \$.01 par value; 90,000 and 60,000 shares authorized, 14,211 and 14,688 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 142 | 147 |
| Additional paid-in-capital | 49,836 | 68,617 |
| Accumulated other comprehensive loss | (5,228 |) (4,784 |

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| | | |
|--|-----------|-----------|
| Retained earnings | 210,515 | 199,511 |
| Total stockholders' equity | 255,265 | 263,491 |
| Total liabilities and stockholders' equity | \$269,264 | \$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 Ended September 30, | | Nine Months Ended September 30, | |
|--|--|----------|---------------------------------------|----------|
| | 2018 | 2017 | 2018 | 2017 |
| Product revenue | \$26,781 | \$27,178 | \$78,581 | \$78,899 |
| Licensing, milestone and contract revenue | 6 | 6 | 18 | 5,133 |
| Total revenue | 26,787 | 27,184 | 78,599 | 84,032 |
| Operating expenses: | | | | |
| Cost of product revenue | 8,282 | 6,250 | 24,279 | 18,648 |
| Research & development | 4,232 | 5,842 | 14,126 | 14,521 |
| Selling, general & administrative | 5,700 | 4,823 | 28,207 | 14,862 |
| Total operating expenses | 18,214 | 16,915 | 66,612 | 48,031 |
| Income from operations | 8,573 | 10,269 | 11,987 | 36,001 |
| Interest and other income, net | 522 | 261 | 907 | 335 |
| Income before income taxes | 9,095 | 10,530 | 12,894 | 36,336 |
| Provision for income taxes | 1,496 | 3,643 | 1,890 | 12,587 |
| Net income | \$7,599 | \$6,887 | \$11,004 | \$23,749 |
| Basic net income per share: | | | | |
| Net income | \$0.53 | \$0.47 | \$0.76 | \$1.63 |
| Basic weighted average common shares outstanding | 14,237 | 14,579 | 14,524 | 14,572 |
| Diluted net income per share: | | | | |
| Net income | \$0.53 | \$0.46 | \$0.74 | \$1.58 |
| Diluted weighted average common shares outstanding | 14,377 | 15,115 | 14,820 | 15,065 |
| Net income | \$7,599 | \$6,887 | \$11,004 | \$23,749 |
| Foreign currency translation adjustment | (113) | 690 | (444) | 2,270 |
| Comprehensive income | \$7,486 | \$7,577 | \$10,560 | \$26,019 |

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

Anika Therapeutics, Inc. and Subsidiaries**Condensed Consolidated Statements of Cash Flows****(in thousands)****(unaudited)**

| | Nine Months Ended September 30, | |
|---|------------------------------------|-----------|
| | 2018 | 2017 |
| Cash flows from operating activities: | | |
| Net income | \$ 11,004 | \$ 23,749 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 4,433 | 3,224 |
| Loss on disposal of fixed assets | 172 | - |
| Stock-based compensation expense | 10,064 | 3,940 |
| Deferred income taxes | (1,205) | 943 |
| Provision for doubtful accounts | (87) | (1) |
| Provision for inventory | 4,073 | 609 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 3,136 | 4,388 |
| Inventories | (5,891) | (4,668) |
| Prepaid expenses, other current and long-term assets | 1,304 | (922) |
| Accounts payable | (2,449) | 2,030 |
| Accrued expenses, other current and long-term liabilities | 509 | (106) |
| Income taxes | (158) | 645 |
| Net cash provided by operating activities | 24,905 | 33,831 |
| Cash flows from investing activities: | | |
| Proceeds from maturity of investments | 34,500 | 31,250 |
| Purchase of investments | (77,683) | (36,500) |
| Purchase of property and equipment | (4,493) | (6,506) |
| Net cash (used in) investing activities | (47,676) | (11,756) |
| 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 | 310 |
| Net cash (used in) provided by financing activities | (28,849) | 310 |
| Exchange rate impact on cash | 189 | 314 |
| (Decrease) Increase in cash and cash equivalents | (51,431) | 22,699 |
| Cash and cash equivalents at beginning of period | 133,256 | 104,261 |

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| | | |
|---|----------|-----------|
| Cash and cash equivalents at end of period | \$81,825 | \$126,960 |
| Supplemental disclosure of cash flow information: | | |
| Non-cash Investing Activities: | | |
| Purchases of property and equipment included in accounts payable and accrued expenses | \$197 | \$1,208 |

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 September 30, 2018, the results of its operations for the three- and nine-month periods ended September 30, 2018 and 2017, and cash flows for the nine-month periods ended September 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 nine-month periods ended September 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 the Company is 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 Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 material additional assets and corresponding liabilities related to the Company's leases on its consolidated balance sheet.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software* (Subtopic 350-40), which amends ASU No. 2015-05, *Customers Accounting for Fees in a Cloud Computing Agreement*, to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The most significant change will align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal-use software license. Accordingly, the amendments in ASU 2018-15 require an entity in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period for all entities. The Company is assessing ASU 2018-15 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. The Company made no adjustments to its previously reported product and total 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 September 30, 2018, deferred revenue was \$52 thousand.

Generally, distributor contracts contain Free on Board (FOB) or Ex-Works (EXW) shipping point 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 & administrative expenses.

Included as a component of product revenue is sales-based royalty revenue, which represents the utilization of the Company's intellectual property licensed by its 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. The Company records royalty revenues based on estimated net sales of licensed products as reported to us by the Company's 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 73% of total Company revenues for the three- and nine-month periods ended September 30, 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 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 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 major product group and primary geographical market. Product revenue by product group was as follows:

| | Three Months Ended September 30, 2018 | | Nine Months Ended September 30, 2018 | |
|----------------|--|----------|---|----------|
| | 2017 | 2018 | 2017 | 2018 |
| Orthobiologics | \$24,097 | \$23,990 | \$69,778 | \$68,686 |

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| | | | | |
|-----------------|----------|----------|----------|----------|
| Surgical | 1,191 | 1,765 | 3,700 | 4,395 |
| Dermal | 80 | 358 | 163 | 1,235 |
| Other | 1,413 | 1,065 | 4,940 | 4,583 |
| Product Revenue | \$26,781 | \$27,178 | \$78,581 | \$78,899 |

Total revenue by geographic location was as follows:

| Geographic Location: | Three Months Ended September 30, 2018 | | 2017 | |
|----------------------|--|-----------------------------|------------------|-----------------------------|
| | Total Revenue | Percentage of Revenue | Total Revenue | Percentage of Revenue |
| United States | \$21,695 | 81 % | \$22,227 | 82 % |
| Europe | 3,132 | 12 % | 2,832 | 10 % |
| Other | 1,960 | 7 % | 2,125 | 8 % |
| Total Revenue | \$26,787 | 100 % | \$27,184 | 100 % |

| | Nine Months Ended September 30, | | | | | |
|----------------------|---------------------------------|------------------|----------|------------------|---------|------------------|
| | 2018 | | | 2017 | | |
| | Total | Percentage of | Total | Percentage of | Total | Percentage of |
| Revenue | Revenue | Revenue | Revenue | Revenue | Revenue | |
| Geographic Location: | | | | | | |
| United States | \$63,377 | 81 % | \$68,624 | 82 % | | |
| Europe | 9,021 | 11 % | 9,743 | 11 % | | |
| Other | 6,201 | 8 % | 5,665 | 7 % | | |
| Total Revenue | \$78,599 | 100 % | \$84,032 | 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 was no indication of any safety or efficacy issue related to the products at this time, the Company removed 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 September 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 investments, including U.S. treasury bills and bank certificates of deposit, totaling \$67.2 million and \$24.0 million as of September 30, 2018 and December 31, 2017, respectively. Unrealized losses and associated tax impact on the Company's available-for-sale securities were immaterial compared to \$0 as of September 30, 2018 and December 31, 2017, respectively.

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.

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

| | | Fair Value Measurements at Reporting Date Using Quoted Prices in | | |
|------------------------------|--------------------|--|-------------------|--------------|
| | | Active Markets | Significant Other | Significant |
| | September 30, 2018 | for Identical Assets | Observable Inputs | Unobservable |
| | | (Level 1) | (Level 2) | Inputs |
| | | | | (Level 3) |
| Cash equivalents: | | | | |
| Money market funds | \$ 7,083 | \$ 7,083 | \$ - | \$ - |
| Investments: | | | | |
| Bank certificates of deposit | \$ 3,500 | \$ - | \$ 3,500 | \$ - |
| U.S. treasury bills | 63,686 | 63,686 | - | - |
| Total investments | \$ 67,186 | \$ 63,686 | \$ 3,500 | \$ - |

| | December 31, 2017 | Fair Value Measurements at Reporting Date Using Quoted Prices in | | |
|------------------------------|-------------------|--|---|---|
| | | Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Cash equivalents: | | | | |
| Money market funds | \$5,893 | \$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 nine-month periods ended September 30, 2018 and 2017 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

| | Nine Months Ended September 30, | | | |
|-------------------------|---------------------------------|----------|--------|----------|
| | 2018 | | 2017 | |
| Risk free interest rate | 2.15% | - 2.82% | 1.60% | - 1.78% |
| Expected volatility | 37.12% | - 45.61% | 41.36% | - 44.30% |
| Expected life (years) | 4.0 | - 4.5 | 4.0 | |
| Expected dividend yield | 0.00% | | 0.00% | |

The Company recorded \$1.2 million and \$1.5 million of stock-based compensation expense for the three-month periods ended September 30, 2018 and 2017, respectively. The Company recorded \$10.1 million and \$3.9 million of stock-based compensation expense for the nine-month periods ended September 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 | | Nine Months | |
|--|---------------|---------|-----------------|---------|
| | Ended | | Ended September | |
| | September 30, | | 30, | |
| | 2018 | 2017 | 2018 | 2017 |
| Cost of product revenue | \$39 | \$107 | \$(205) | \$306 |
| Research and development | 239 | 177 | 690 | 340 |
| Selling, general and administrative | 899 | 1,190 | 9,579 | 3,294 |
| Total stock-based compensation expense | \$1,177 | \$1,474 | \$10,064 | \$3,940 |

The decrease in stock-based compensation expense within the cost of product revenue line item during the three- and nine-month periods ended September 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 stock-based compensation awards granted and exercised during the three- and nine-month periods ended September 30, 2018 and 2017:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------|--|--------|------------------------------------|---------|
| | 2018 | 2017 | 2018 | 2017 |
| Grants: | | | | |
| Stock options | 18,500 | 60,609 | 228,300 | 470,744 |
| RSAs | - | 14,506 | 64,578 | 14,506 |
| RSUs | 3,624 | - | 11,754 | 9,970 |
| Exercises: | | | | |
| Stock options | - | 3,329 | 284,548 | 12,766 |
| SARs | - | - | - | 5,000 |

During the three- and nine-month periods ended September 30, 2018 and 2017, the Company granted stock-based compensation 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 grants of RSUs to its non-employee directors. 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 September 30, | Nine Months Ended September 30, |
|--|---------------------------------------|
|--|---------------------------------------|

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| | 2018 | 2017 | 2018 | 2017 |
|--|--------|--------|--------|--------|
| Shares used in the calculation of basic earnings per share | 14,237 | 14,579 | 14,524 | 14,572 |
| Effect of dilutive securities: | | | | |
| Stock options, SARs, RSUs and RSAs | 140 | 536 | 296 | 493 |
| Diluted shares used in the calculation of earnings per share | 14,377 | 15,115 | 14,820 | 15,065 |

Stock options of 0.9 million and 0.5 million shares were outstanding for the three-month periods ended September 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 shares were outstanding for the nine-month periods ended September 30, 2018 and 2017 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 was approximately 60% of the then estimated total number of shares expected to be repurchased under the ASR Agreement.

On July 16, 2018, the Company settled the 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. Pursuant to the terms of the ASR Agreement, the final number of shares and the average purchase price was determined at the end of the applicable purchase period, which was July 16, 2018. 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, 2016. The Company will not make further purchases under the program. In total, 0.8 million shares were repurchased under the ASR Agreement at an average repurchase price of \$37.18 per share. These shares are held by the Company as authorized but unissued shares. All shares were repurchased in accordance with the publicly announced program, and the Company will not make any further purchases under the program. The initial and final 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.

8. Inventories

Inventories consist of the following:

| | September 30, 2018 | December 31, 2017 |
|-----------------|--------------------------|-------------------------|
| Raw materials | \$ 13,241 | \$ 11,296 |
| Work-in-process | 5,948 | 6,062 |
| Finished goods | 4,639 | 4,677 |
| Total | \$ 23,828 | \$ 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 a net inventory reserve of \$1.4 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 nine-month period ended September 30, 2018.

9. Intangible Assets

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

| | Gross Value | September 30, 2018 | | | December 31, 2017 | | | Useful Life |
|-----------------------------------|----------------|--|-----------------------------|----------------------|--|-----------------------------|----------------------|----------------|
| | | Accumulated Currency Translation Adjustment | Accumulated Amortization | Net Book Value | Accumulated Currency Translation Adjustment | Accumulated Amortization | Net Book Value | |
| Developed technology | \$ 17,100 | \$(2,744) | \$(8,443) | \$ 5,913 | \$(2,550) | \$(7,723) | \$ 6,827 | 15 |
| In-process research & development | 4,406 | (1,122) | - | 3,284 | (1,015) | - | 3,391 | Indefinite |
| Distributor relationships | 4,700 | (415) | (4,285) | - | (415) | (4,285) | - | 5 |
| Patents | 1,000 | (164) | (469) | 367 | (152) | (431) | 417 | 16 |
| Eleves trade name | 1,000 | - | (1,000) | - | - | (1,000) | - | 9 |
| Total | \$ 28,206 | \$(4,445) | \$(14,197) | \$ 9,564 | \$(4,132) | \$(13,439) | \$ 10,635 | |

The aggregate amortization expense related to intangible assets was \$0.2 million for the three-month periods ended September 30, 2018 and 2017. The aggregate amortization expense related to intangible assets was \$0.8 million and \$0.7 million for the nine- month periods September 30, 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 September 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:

| | |
|--|-----------------------|
| | September 30, 2018 |
| Balance at January 1, 2018 | \$ 8,218 |
| Effect of foreign currency adjustments | (259) |
| Balance at September 30, 2018 | \$ 7,959 |

11. Accrued Expenses

Accrued expenses consist of the following:

| | September 30, 2018 | December 31, 2017 |
|---|--------------------------|-------------------------|
| Compensation and related expenses | \$ 3,875 | \$ 2,893 |
| Clinical trial costs | 586 | 2,318 |
| Accrued liabilities related to product recall | 344 | - |
| Research grants | 406 | 419 |
| Professional fees | 1,233 | 448 |
| Deferred revenue | 52 | - |
| Other | 347 | 248 |
| Total | \$ 6,843 | \$ 6,326 |

Included in Compensation and related expenses as of September 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. 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. On the same date, the Company and the former Chief Executive Officer entered into a release agreement related to terms in his employment agreement. Under the terms of these agreements, 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. 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 \$0.3 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 September 30, 2018 or December 31, 2017, 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 \$1.5 million and \$1.9 million for the three- and nine-month periods ended September 30, 2018, based on effective tax rates of 16.4% and 14.7%, respectively. Provisions for income taxes were \$3.6 million and \$12.6 million for the three- and nine-month periods ended September 30, 2017, based on an effective tax rate of 34.6%. The net decrease in the effective tax rate for the three- and nine-month periods ended September 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 of 2017 ("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, the Company realized a windfall tax benefit for the nine-month period ended September 30, 2018 related to exercises of employee equity awards resulting in a discrete period income tax benefit of \$1.6 million and a reduction in the effective tax rate of 12.1%. The Company realized a \$0.1 million windfall tax benefit for the three-month period ended September 30, 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 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 September 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 Tax Act, the Company has recorded the impact on the condensed consolidated financial statements. There were no significant changes in the provision amount recorded in 2017 related to the finalization of the Company’s analysis. The other provisions of the Tax Act did not have a material impact on the 2017 consolidated financial statements.

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. For near-term opportunities in the U.S. market, we are evaluating a potential hybrid commercial approach that would see us balance a small direct model with an optimal form of strategic partnership. For longer-term 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.

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 September 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 nine-month period ended September 30, 2018. In addition, we incurred \$0.6 million for future expenses associated with the administration and remediation of the voluntary recall. As of September 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. In the third quarter of 2017, 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. The first patients were enrolled in this follow-up study in the fourth quarter of 2017 and we completed the nine-month patient follow-up in the third quarter of 2018. 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 completing the analysis of 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, which received CE Mark approval in September 2009, 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, which was aimed at 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. Given the changing medical landscape with respect to the randomization arm for this trial, the microfracture procedure, we are actively pursuing alternative strategies to accelerate patient enrollment.

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 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 and we expect will commence in 2019. 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, an injectable, self-setting, osteoconductive bone graft substitute that is reabsorbed by the body and replaced by the growth of new bone during the healing process. 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. This implant could be used to repair partial and full-thickness rotator cuff tears, and we expect to have a fully-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 was 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 it was terminated in October 2018 after discussions between the parties. 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

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|------------------------------------|----------|-----------------|----------------|------------------------------------|----------|-----------------|----------------|
| | 2018 | 2017 | \$ Inc/(Dec) | % Inc/(Dec) | 2018 | 2017 | \$ Inc/(Dec) | % Inc/(Dec) |
| | (in thousands, except percentages) | | | | (in thousands, except percentages) | | | |
| Product revenue | \$26,781 | \$27,178 | \$(397) | (1)% | \$78,581 | \$78,899 | \$(318) | (0)% |
| Licensing, milestone and contract revenue | 6 | 6 | - | 0% | 18 | 5,133 | (5,115) | * |
| Total revenue | 26,787 | 27,184 | (397) | (1)% | 78,599 | 84,032 | (5,433) | (6)% |
| Operating expenses: | | | | | | | | |
| Cost of product revenue | 8,282 | 6,250 | 2,032 | 33% | 24,279 | 18,648 | 5,631 | 30% |
| Research and development | 4,232 | 5,842 | (1,610) | (28)% | 14,126 | 14,521 | (395) | (3)% |
| Selling, general & administrative | 5,700 | 4,823 | 877 | 18% | 28,207 | 14,862 | 13,345 | 90% |
| Total operating expenses | 18,214 | 16,915 | 1,299 | 8% | 66,612 | 48,031 | 18,581 | 39% |
| Income from operations | 8,573 | 10,269 | (1,696) | (17)% | 11,987 | 36,001 | (24,014) | (67)% |
| Interest and other income, net | 522 | 261 | 261 | 100% | 907 | 335 | 572 | 171% |
| Income before income taxes | 9,095 | 10,530 | (1,435) | (14)% | 12,894 | 36,336 | (23,442) | (65)% |
| Provision for income taxes | 1,496 | 3,643 | (2,147) | (59)% | 1,890 | 12,587 | (10,697) | (85)% |
| Net income | \$7,599 | \$6,887 | \$712 | 10% | \$11,004 | \$23,749 | \$(12,745) | (54)% |
| Product gross profit | \$18,499 | \$20,928 | \$(2,429) | (12)% | \$54,302 | \$60,251 | \$(5,949) | (10)% |
| Product gross margin | 69% | 77% | | | 69% | 76% | | |

* Percentage increase has been omitted due to magnitude.

Product Revenue

Product revenue for the three-month period ended September 30, 2018 was \$26.8 million, a decrease of \$0.4 million as compared to \$27.2 million for the three-month period ended September 30, 2017. Product revenue for the nine-month period ended September 30, 2018 was \$78.6 million, a decrease of \$0.3 million as compared to \$78.9 million for the nine-month period ended September 30, 2017. For the nine-month period ended September 30, 2018, the decrease in product revenue was mainly driven by a decline in ORTHOVISC revenue and the effects of the previously-described voluntary recall of certain production lots of our HYAFF-based products, partially offset by increases in MONOVSC and CINGAL revenue.

The following tables present product revenue by product group:

| | Three Months Ended September 30, | | | | |
|----------------|------------------------------------|----------|-----------|-----------|----|
| | 2018 | 2017 | \$ | % | |
| | | | Inc/(Dec) | Inc/(Dec) | |
| | (in thousands, except percentages) | | | | |
| Orthobiologics | \$24,097 | \$23,990 | \$ 107 | 0 | % |
| Surgical | 1,191 | 1,765 | (574) | (33 | %) |
| Dermal | 80 | 358 | (278) | (78 | %) |
| Other | 1,413 | 1,065 | 348 | 33 | % |
| Total | \$26,781 | \$27,178 | \$ (397) | (1 | %) |

| | Nine Months Ended September 30, | | | | |
|----------------|------------------------------------|----------|-----------|-----------|----|
| | 2018 | 2017 | \$ | % | |
| | | | Inc/(Dec) | Inc/(Dec) | |
| | (in thousands, except percentages) | | | | |
| Orthobiologics | \$69,778 | \$68,686 | \$ 1,092 | 2 | % |
| Surgical | 3,700 | 4,395 | (695) | (16 | %) |
| Dermal | 163 | 1,235 | (1,072) | (87 | %) |
| Other | 4,940 | 4,583 | 357 | 8 | % |
| Total | \$78,581 | \$78,899 | \$ (318) | (0 | %) |

Orthobiologics

Our orthobiologics franchise consists of our orthopedic pain management and regenerative therapies. Overall, sales were flat for the three-month period ended September 30, 2018, as compared to the same period in 2017, as a result of increased unit demand offset by a decline in pricing in the U.S. For the nine-month period ended September 30, 2018, sales increased by \$1.1 million as compared to the same period in 2017. The overall increase in the nine-month period ended September 30, 2018 was primarily due to strong growth in domestic MONOVISC revenue and international CINGAL revenue offset in part by declines in worldwide ORTHOVISC revenue. The growth of U.S. MONOVISC revenue 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 declines in ORTHOVISC revenue, U.S. viscosupplement 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 declined \$0.6 million and \$0.7 million, respectively, for the three- and nine-month periods ended September 30, 2018 to \$1.2 million and \$3.7 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 and a decrease in sales of our surgical anti-adhesion products. We expect surgical product revenue to decrease modestly in 2018 as compared to 2017 primarily due to decreased worldwide sales of our ENT and 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 nine-month periods ended September 30, 2018, dermal product sales decreased \$0.3 million and \$1.1 million, respectively, as compared to the same periods in 2017 due to the voluntary recall of certain production lots of our HYAFF-based products previously described. As a result, we expect dermal revenue to decrease in 2018 as compared to 2017.

Other

Other product revenue includes revenues from our ophthalmic and veterinary franchises. Other product revenue increased for the three-month period ended September 30, 2018 by \$0.3 million and increased for the nine-month period ended September 30, 2018 by \$0.4 million or 8%, both as compared to the same periods in 2017. We expect other revenue to increase in 2018 as compared to 2017, primarily driven by increases in ophthalmic revenue.

Licensing, Milestone and Contract Revenue

Licensing, milestone and contract revenue for the three- and nine-month periods ended September 30, 2018 was \$6 thousand and \$18 thousand, as compared to \$6 thousand and \$5.1 million for the same periods in 2017. Revenue for the nine-month period ended September 30, 2017 included a \$5.0 million milestone payment associated with our U.S. license agreement with Mitek for MONOVISC that was received and fully recognized as a result of U.S. MONOVISC 12-month end-user sales exceeding \$100.0 million.

Product Gross Profit and Margin

Product gross profit for the three- and nine-month periods ended September 30, 2018 decreased \$2.4 million and \$5.9 million to \$18.5 million and \$54.3 million, respectively, representing 69% of product revenue for each period. Product gross profit for the three- and nine-month periods ended September 30, 2017 was \$20.9 million and \$60.3 million, respectively, or 77% and 76% of product revenue for the periods. The decrease in product gross margin for the three-month period ended September 30, 2018, as compared to the same period in 2017, was due to higher production costs, revenue mix, including the impact of pricing declines for our ORTHOVISC and MONOVISC products in the U.S., and certain period costs related to inventory reserve charges. The decrease in product gross margin for the nine-month period ended September 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 production costs, revenue mix and pricing dynamics, and voluntary recall related charges. 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 nine-month periods ended September 30, 2018 were \$4.2 million and \$14.1 million, representing 16% and 18% of total revenue for the respective periods, a decrease of \$1.6 million and \$0.4 million, respectively, as compared to the same periods in 2017. The decrease in research and development expenses was primarily due to the completion of our CINGAL 16-02 Study in the second quarter of 2018. The decrease was partially offset by increased pre-clinical product development activities associated with certain product candidates in our research and development pipeline, including our new rotator cuff product candidate. 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 nine-month periods ended September 30, 2018 were \$5.7 million and \$28.2 million, representing 21% and 36% of total revenue for the respective periods, an increase of \$0.9 million and \$13.3 million as compared to the same periods in 2017. The increase in SG&A expenses for the three-month period ending September 30, 2018 was primarily related to increased personnel costs and external professional fees. SG&A expenses increased for the nine-month period ending September 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 \$1.5 million and \$1.9 million for the three- and nine-month periods ended September 30, 2018, based on effective tax rates of 16.4% and 14.7%, respectively. Provisions for income taxes were \$3.6 million and \$12.6 million for the three- and nine-month periods ended September 30, 2017, based on an effective tax rate of 34.6%. The net decrease in the effective tax rate for the three- and nine-month periods ended September 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 of 2017 (“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, the Company realized a windfall tax benefit for the nine-month period ended September 30, 2018 related to exercises of employee equity awards resulting in a discrete period income tax benefit of \$1.6 million and a reduction in the effective tax rate of 12.1%. The Company realized a \$0.1 million windfall tax benefit for the three-month period ended September 30, 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 \$149.0 million and \$157.3 million, and working capital totaled \$186.3 million and \$193.3 million as of September 30, 2018 and December 31, 2017, respectively. In addition, as of September 30, 2018, we have \$50.0 million of available credit under our senior revolving credit facility with Bank of America, N.A. 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 September 30, 2018, we were in compliance with the terms of our credit agreement with Bank of America, N.A.

Cash provided by operating activities was \$24.9 million for the nine-month period ended September 30, 2018, as compared to cash provided by operating activities of \$33.8 million for the same period in 2017. The decrease in cash provided by operations for the nine-month period ended September 30, 2018, as compared to the same period in 2017, was primarily related to our higher operating expenses in manufacturing operations, sales and marketing, decrease in accounts payable, and an increase in inventory on hand.

Cash used in investing activities was \$47.7 million for the nine-month period ended September 30, 2018, as compared to cash used in investing activities of \$11.8 million for the same period in 2017. The increase was due to increased purchases of investments, partially offset by lower capital expenditures as compared to 2017.

Cash used in financing activities was \$28.8 million for the nine-month period ended September 30, 2018, as compared to cash used in financing activities of \$0.3 million for the same period in 2017. The decrease in cash used in financing activities for the nine-month period ended September 30, 2018 was primarily attributable to the utilization of \$30.0 million cash to repurchase outstanding common stock under the previously-discussed Fixed Dollar Accelerated Share Repurchase program and \$1.7 million of vested RSAs that were withheld for individual taxes and retired. This was partially offset by \$2.9 million of proceeds received from the exercise of stock-based compensation awards.

Critical Accounting Policies and Estimates

There were no other significant changes in our critical accounting policies during the nine months ended September 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 to the condensed financial statements included in this Quarterly Report on Form 10-Q.

There were no other significant changes in our critical accounting estimates during the nine months ended September 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 \$2.0 million of retirement and post-retirement consulting benefits 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 nine months ended September 30, 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 nine 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 nine-month period ended September 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 and our Quarterly Reports on Form 10-Q 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 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 the pathway to commercialize our CINGAL product in the United States, and we may face other unforeseen difficulties and delays in implementing new commercial models for CINGAL and other products, which could affect our business and financial results.

In the first half of 2018, we began the initial, pre-launch phases of implementing a direct sales model to commercialize and promote CINGAL in the United States. 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 initially intended to use a direct sales model, at least in part, to potentially commercialize CINGAL and other of our products in the United States in the future. Given the delay of a potential CINGAL regulatory approval, we reevaluated our commercial strategy for our products in the U.S. market. In general, we believe that the hybrid of small direct and partnership distribution models will maximize the revenue potential from our current and near-term future product portfolio. We have ceased additional U.S. direct sales pre-launch activities for CINGAL as we evaluate its regulatory pathway in the United States. For longer-term 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 cannot assure you that there will not be unforeseen roadblocks or delays in the implementation of any commercial model, and we cannot be certain that any given commercial model for any specific product will maximize the revenues to be generated for us by such product. Failure to effectively implement any commercial model for CINGAL or other future products could materially impact our competitive position, business, and financial results.

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 us. 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.

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 September 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 September 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) |
|-------------------------|--|--|---|--|
| July 1 to 31, 2018 | 372,140 | - | 372,140 | \$ - |
| August 1 to 31, 2018 | - | - | - | \$ - |
| September 1 to 30, 2018 | - | - | - | \$ - |
| Total | 372,140 | | 372,140 | |

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 19, 2018, and we will not make further purchases under the program.

ITEM 6. EXHIBITS

Exhibit No. Description

- (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 September 30, 2018, as filed with the SEC on October 26, 2018, formatted in XBRL (eXtensible Business Reporting Language), as follows:
- i. Condensed Consolidated Balance Sheets as of September 30, 2018 (unaudited) and December 31, 2017 (unaudited)
 - ii. Condensed Consolidated Statements of Operations and Comprehensive Income for the Three and Nine Months Ended September 30, 2018 and September 30, 2017 (unaudited)
 - iii. Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and September 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: October 26, 2018 By: /s/ SYLVIA CHEUNG
Sylvia Cheung
Chief Financial Officer
(Authorized Officer and
Principal Financial
Officer)