

Anika Therapeutics, Inc.
Form 10-Q
July 28, 2017

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
X ACT OF 1934**

For the quarterly period ended June 30, 2017

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

For the transition period from to

Commission File Number 000-21326

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts
(State or Other Jurisdiction of
Incorporation or Organization)

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

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

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes o No o

APPLICABLE ONLY TO CORPORATE ISSUERS:

As of July 20, 2017 there were 14,658,440 outstanding shares of Common Stock, par value \$.01 per share.

ANIKA THERAPEUTICS, INC.

TABLE OF CONTENTS

| | Page |
|-------------------|---|
| <u>Part I</u> | <u>Financial Information</u> |
| <u>Item 1.</u> | <u>Financial Statements (unaudited):</u> |
| | 3 |
| | <u>Condensed Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016</u> |
| | 3 |
| | <u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three- and six-month periods ended June 30, 2017 and 2016</u> |
| | 4 |
| | <u>Condensed Consolidated Statements of Cash Flows for the six-month period ended June 30, 2017 and 2016</u> |
| | 5 |
| | <u>Notes to Condensed Consolidated Financial Statements</u> |
| | 6 |
| <u>Item 2.</u> | <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> |
| | 14 |
| <u>Item 3.</u> | <u>Quantitative and Qualitative Disclosures About Market Risk</u> |
| | 19 |
| <u>Item 4.</u> | <u>Controls and Procedures</u> |
| | 19 |
| <u>Part II</u> | <u>Other Information</u> |
| <u>Item 1.</u> | <u>Legal Proceedings</u> |
| | 19 |
| <u>Item 1A.</u> | <u>Risk Factors</u> |
| | 19 |
| <u>Item 6.</u> | <u>Exhibits</u> |
| | 20 |
| <u>Signatures</u> | 21 |

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

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

ANIKA, ANIKA THERAPEUTICS, CINGAL, HYAFF, MONOVISC, and ORTHOVISC are our registered trademarks. This Quarterly Report on Form 10-Q also contains registered marks, trademarks, and trade names that are the property of other companies and licensed to us.

PART I: FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS**

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands, except share data and per share data)

(unaudited)

| ASSETS | June 30, 2017 | December 31, 2016 |
|---|------------------|----------------------|
| Current assets: | | |
| Cash and cash equivalents | 117,874 | 104,261 |
| Investments | 25,000 | 20,500 |
| Accounts receivable, net of reserves of \$210 and \$194 at June 30, 2017 and December 31, 2016, respectively | 30,450 | 27,598 |
| Inventories, net | 17,584 | 15,983 |
| Prepaid expenses and other current assets | 1,973 | 2,098 |
| Total current assets | 192,881 | 170,440 |
| Property and equipment, net | 52,272 | 52,296 |
| Long-term deposits and other | 1,389 | 69 |
| Intangible assets, net | 10,626 | 10,227 |
| Goodwill | 7,836 | 7,214 |
| Total assets | \$265,004 | \$ 240,246 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$5,465 | \$ 2,303 |
| Accrued expenses and other current liabilities | 5,673 | 6,496 |
| Income taxes payable | 2,303 | - |
| Total current liabilities | 13,441 | 8,799 |
| Other long-term liabilities | 422 | 2,126 |
| Deferred tax liability | 7,003 | 6,548 |
| Commitments and contingencies (Note 12) | - | |
| Stockholders' equity: | | |
| Preferred stock, \$.01 par value; 1,250 shares authorized, no shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively | - | - |
| Common stock, \$.01 par value; 60,000 shares authorized, 14,658 and 14,627 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively | 146 | 146 |
| Additional paid-in-capital | 65,171 | 61,735 |
| Accumulated other comprehensive loss | (5,736) | (7,317) |

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

| | | |
|--|-----------|------------|
| Retained earnings | 184,557 | 168,209 |
| Total stockholders' equity | 244,138 | 222,773 |
| Total liabilities and stockholders' equity | \$265,004 | \$ 240,246 |

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

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Income

(in thousands, except per share data)

(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|-----------------------------|-----------|---------------------------|-----------|
| | 2017 | 2016 | 2017 | 2016 |
| Product revenue | \$ 28,340 | \$ 26,575 | \$ 51,721 | \$ 48,853 |
| Licensing, milestone and contract revenue | 5,122 | 6 | 5,127 | 11 |
| Total revenue | 33,462 | 26,581 | 56,848 | 48,864 |
| Operating expenses: | | | | |
| Cost of product revenue | 6,315 | 6,065 | 12,398 | 11,490 |
| Research and development | 4,449 | 2,792 | 8,679 | 4,951 |
| Selling, general and administrative | 4,972 | 4,255 | 10,039 | 8,245 |
| Total operating expenses | 15,736 | 13,112 | 31,116 | 24,686 |
| Income from operations | 17,726 | 13,469 | 25,732 | 24,178 |
| Interest income, net | 16 | 49 | 74 | 121 |
| Income before income taxes | 17,742 | 13,518 | 25,806 | 24,299 |
| Provision for income taxes | 6,373 | 4,903 | 8,944 | 8,789 |
| Net income | \$ 11,369 | \$ 8,615 | \$ 16,862 | \$ 15,510 |
| Basic net income per share: | | | | |
| Net income | \$ 0.78 | \$ 0.59 | \$ 1.16 | \$ 1.05 |
| Basic weighted average common shares outstanding | 14,588 | 14,679 | 14,582 | 14,778 |
| Diluted net income per share: | | | | |
| Net income | \$ 0.76 | \$ 0.57 | \$ 1.12 | \$ 1.02 |
| Diluted weighted average common shares outstanding | 15,044 | 15,111 | 15,046 | 15,210 |
| Net income | \$ 11,369 | \$ 8,615 | \$ 16,862 | \$ 15,510 |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation adjustment | 1,289 | (536) | 1,581 | 238 |
| Comprehensive income | \$ 12,658 | \$ 8,079 | \$ 18,443 | \$ 15,748 |

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

Anika Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

| | Six Months Ended June 30, | |
|---|---------------------------|-----------|
| | 2017 | 2016 |
| Cash flows from operating activities: | | |
| Net income | \$ 16,862 | \$ 15,510 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 2,022 | 1,901 |
| Stock-based compensation expense | 2,465 | 1,478 |
| Deferred income taxes | 589 | (252) |
| Provision for doubtful accounts | (1) | 52 |
| Provision for inventory | 287 | 181 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (2,449) | (2,932) |
| Inventories | (1,741) | (2,438) |
| Prepaid expenses, other current and long-term assets | (155) | 186 |
| Accounts payable | 2,362 | (4,252) |
| Accrued expenses and other current liabilities | (182) | 446 |
| Income taxes | 2,303 | (3,169) |
| Other long-term liabilities | (631) | 351 |
| Net cash provided by operating activities | 21,731 | 7,062 |
| Cash flows from investing activities: | | |
| Proceeds from maturity of investments | 20,000 | 27,750 |
| Purchase of investments | (24,500) | (22,499) |
| Purchase of property and equipment | (3,917) | (9,869) |
| Net cash used in investing activities | (8,417) | (4,618) |
| Cash flows from financing activities: | | |
| Repurchases of common stock | - | (25,000) |
| Proceeds from exercise of equity awards | 209 | 922 |
| Net cash provided by (used in) financing activities | 209 | (24,078) |
| Exchange rate impact on cash | 90 | 52 |
| Increase (decrease) in cash and cash equivalents | 13,613 | (21,582) |
| Cash and cash equivalents at beginning of period | 104,261 | 110,707 |
| Cash and cash equivalents at end of period | \$ 117,874 | \$ 89,125 |
| Supplemental disclosure of cash flow information: | | |
| Non-cash Investing Activities: | | |

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

| | | |
|---|----------|----------|
| Purchases of property and equipment included in accounts payable and accrued expenses | \$ 1,193 | \$ 2,128 |
| Build-to-suit lease agreement | \$ - | \$ 482 |

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

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

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) and in accordance with accounting principles generally accepted in the United States (“US GAAP”). The financial statements include the accounts of Anika Therapeutics, Inc. and its subsidiaries. Inter-company transactions and balances have been eliminated. 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, 2016 balances reported herein are derived from the audited consolidated financial statements. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the condensed consolidated financial position of the Company as of June 30, 2017, the results of its operations for the three- and six-month periods ended June 30, 2017 and 2016, and cash flows for the six-month periods ended June 30, 2017 and 2016.

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, 2016. The results of operations for the six-month periods ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017. Certain prior period amounts have been reclassified to conform to the current period presentation. This change in classification does not materially affect previously reported cash flows from operations or from financing activities in the Condensed Consolidated Statement of Cash Flows, and had no effect on the previously reported Condensed Consolidated Statement of Operations and Comprehensive Income.

3. Recent Accounting Pronouncements

Recently Issued

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In July 2015, the FASB issued a one-year deferral of ASU 2014-09 making it effective for annual reporting periods beginning on or after December 15, 2017, while also providing for early adoption not to occur before the original effective date. The Company currently intends to adopt the new standard on a modified retrospective basis with the cumulative effect of the change reflected in retained earnings as of January 1, 2018 and to not restate prior periods. The Company has commenced work to assess the impact of the new revenue standard on its principal revenue streams. The Company has not made a determination as to the impact the adoption will have on its consolidated financial statements.

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

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments (Topic 326) Credit Losses*. ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income are to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. ASU 2016-13 is effective as of January 1, 2020. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements or footnote disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment*. ASU 2017-04 will simplify the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. Current guidance requires that companies compute the implied fair value of goodwill under Step 2 by performing procedures to determine the fair value at the impairment testing date of its assets and liabilities (including unrecognized assets and liabilities) following the procedure that would be required in determining the fair value of assets acquired and liabilities assumed in a business combination. This standard will require companies to perform annual or interim goodwill impairment tests by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This standard will be effective for annual periods beginning after December 15, 2019, including interim periods occurring after that date, and will be applied prospectively. Early adoption of this standard is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements or footnote disclosures.

Recently Adopted

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718)*. ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 is effective as of January 1, 2017. Since January 1, 2017, the Company has recognized excess tax benefits and tax deficiencies related to share-based payments in the Condensed Consolidated Statements of Operations and Comprehensive Income as a component of the provision for income taxes on a prospective basis. Such excess tax benefits and tax deficiencies were previously recorded in equity. The Company also began presenting tax-related cash flows resulting from share-based payments as operating activities in the Condensed Consolidated Statements of Cash Flows, and revised retrospectively prior periods to reflect this provision. Accordingly, the Condensed Consolidated Statement of Cash Flows for the six months ended June 30, 2016 was revised by increasing net cash provided by operating activities by \$0.4 million and by decreasing net cash used in financing activities by \$0.4 million. Lastly, as of January 1, 2017, the Company elected to recognize forfeitures as they occur rather than estimate forfeitures each period on a modified retrospective basis. See Notes 6 and 14 for additional information regarding the impacts on the condensed consolidated financial statements.

4. Investments

All of the Company's investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income, net of related income taxes. The Company held bank certificates of deposit of \$25.0 million and \$20.5 million at June 30, 2017 and December 31, 2016, respectively. There were no unrealized gains or losses on the Company's available-for-sale securities at June 30, 2017 or December 31, 2016.

5. Fair Value Measurements

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants based on assumptions that market participants would use in pricing an asset or liability. As a basis for classifying the fair value measurements, a three-tier fair value hierarchy, which classifies the fair value measurements based on the inputs used in measuring fair value, was established as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets or liabilities; (Level 2) significant other observable inputs that are observable either directly or indirectly; and (Level 3) significant unobservable inputs for which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, the Company records its investments at fair value.

The Company's investments are all classified within Level 2 of the fair value hierarchy. These investments classified within Level 2 of the fair value hierarchy are valued based on matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk.

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

| | | Fair Value Measurements at Reporting Date Using | | |
|--------------------|---------------|--|---|---|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Observable Inputs (Level 2) | Other Significant Unobservable Inputs (Level 3) |
| | June 30, 2017 | | | |
| Cash equivalents: | | | | |
| Money market funds | \$ 66,244 | \$ - | \$ 66,244 | \$ - |
| Investments: | | | | |