# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2017**

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

**For the transition period from to _____ to**

**Commission File Number: 001-35076**

# NAVIDEA BIOPHARMACEUTICALS, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **31-1080091** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(IRS Employer Identification No.)** |
| **4995 Bradenton Avenue, Suite 240, Dublin, Ohio** | **43017-3552** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**(614) 793-7500**
**(Registrant's telephone number, including area code)**

**(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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☒ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| Emerging Growth 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 12-b-2 of the Act.) Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 162,256,646 shares of common stock, par value $.001 per share (as of the close of business on November 1, 2017).

**NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES**

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**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**
**Consolidated Balance Sheets**

| | September 30, 2017 (unaudited) | December 31, 2016 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 4,619,649 | $ 1,539,325 |
| Restricted cash | — | 5,001,253 |
| Available-for-sale securities | 1,998,800 | — |
| Accounts and other receivables | 8,042,691 | 203,016 |
| Inventory, net | — | 96,208 |
| Prepaid expenses and other | 504,971 | 842,220 |
| Assets associated with discontinued operations, current | — | 3,144,247 |
| Total current assets | 15,166,111 | 10,826,269 |
| Property and equipment | 1,712,342 | 3,232,372 |
| Less accumulated depreciation and amortization | 1,399,040 | 2,051,787 |
| Property and equipment, net | 313,302 | 1,180,585 |
| Patents, trademarks and license agreements | 480,404 | 146,685 |
| Less accumulated amortization | 14,832 | — |
| Patents, trademarks and license agreements, net | 465,572 | 146,685 |
| Guaranteed earnout receivable | 6,445,390 | — |
| Other assets | 215,332 | 202,882 |
| Assets associated with discontinued operations | — | 105,255 |
| Total assets | $ 22,605,707 | $ 12,461,676 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,231,075 | $ 5,165,385 |
| Accrued liabilities and other | 2,494,115 | 7,872,893 |
| Notes payable, current | 1,981,676 | 51,957,913 |
| Terminated lease liability, current | 144,231 | — |
| Liabilities associated with discontinued operations, current | 33,141 | 4,865,597 |
| Total current liabilities | 5,884,238 | 69,861,788 |
| Notes payable | — | 9,641,179 |
| Terminated lease liability | 629,445 | — |
| Other liabilities | 76,850 | 624,922 |
| Total liabilities | 6,590,533 | 80,127,889 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity (deficit): | | |
| Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at September 30, 2017 and December 31, 2016 | — | — |
| Common stock; $.001 par value; 300,000,000 shares authorized; 162,206,646 and 155,762,729 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively | 162,207 | 155,763 |
| Additional paid-in capital | 331,036,285 | 326,564,148 |
| Accumulated deficit | (315,850,836) | (394,855,034) |
| Accumulated other comprehensive loss | (1,200) | — |
| Total Navidea stockholders' equity (deficit) | 15,346,456 | (68,135,123) |
| Noncontrolling interest | 668,718 | 468,910 |
| Total stockholders' equity (deficit) | 16,015,174 | (67,666,213) |
| Total liabilities and stockholders' equity (deficit) | $ 22,605,707 | $ 12,461,676 |

See accompanying notes to consolidated financial statements.

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**
**Consolidated Statements of Operations**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| Revenue: | | | | |
| Tc99m tilmanocept sales revenue | $ — | $ 17,601 | $ — | $ 30,800 |
| Tc99m tilmanocept license revenue | — | 1,295,625 | 100,000 | 1,795,625 |
| Grant and other revenue | 223,669 | 510,974 | 1,315,298 | 2,113,420 |
| Total revenue | 223,669 | 1,824,200 | 1,415,298 | 3,939,845 |
| Cost of goods sold | — | 2,889 | — | 5,185 |
| Gross profit | 223,669 | 1,821,311 | 1,415,298 | 3,934,660 |
| Operating expenses: | | | | |
| Research and development | 874,547 | 919,441 | 2,765,695 | 5,010,923 |
| Selling, general and administrative | 1,734,707 | 1,811,680 | 9,006,725 | 5,832,623 |
| Total operating expenses | 2,609,254 | 2,731,121 | 11,772,420 | 10,843,546 |
| Loss from operations | (2,385,585) | (909,810) | (10,357,122) | (6,908,886) |
| Other income (expense): | | | | |
| Interest income (expense), net | 76,050 | 159 | 144,811 | (2,076) |
| Equity in loss of R-NAV, LLC | — | — | — | (15,159) |
| Loss on disposal of investment in R-NAV, LLC | — | — | — | (39,732) |
| Change in fair value of financial instruments | — | (839,298) | 153,357 | 1,755,989 |
| Loss on extinguishment of debt | — | — | (1,314,102) | — |
| Other, net | (6,979) | (12,498) | (45,256) | (49,916) |
| Total other income (expense), net | 69,071 | (851,637) | (1,061,190) | 1,649,106 |
| Loss before income taxes | (2,316,514) | (1,761,447) | (11,418,312) | (5,259,780) |
| Benefit from income taxes | 775,750 | — | 3,861,156 | — |
| Loss from continuing operations | (1,540,764) | (1,761,447) | (7,557,156) | (5,259,780) |
| Discontinued operations, net of tax effect: | | | | |
| Income (loss) from discontinued operations | 5,399 | 1,701,911 | (332,838) | (5,167,312) |
| Gain on sale | 145,877 | — | 86,894,000 | — |
| Net income (loss) | (1,389,488) | (59,536) | 79,004,006 | (10,427,092) |
| Less loss attributable to noncontrolling interest | (23) | (159) | (192) | (516) |
| Net income (loss) attributable to common stockholders | $ (1,389,465) | $ (59,377) | $ 79,004,198 | $ (10,426,576) |
| Income (loss) per common share (basic): | | | | |
| Continuing operations | $ (0.01) | $ (0.01) | $ (0.05) | $ (0.03) |
| Discontinued operations | $ — | $ 0.01 | $ 0.54 | $ (0.04) |
| Attributable to common stockholders | $ (0.01) | $ — | $ 0.49 | $ (0.07) |
| Weighted average shares outstanding (basic) | 162,006,646 | 155,481,278 | 161,437,276 | 155,390,911 |
| Income (loss) per common share (diluted): | | | | |
| Continuing operations | $ (0.01) | $ (0.01) | $ (0.05) | $ (0.03) |
| Discontinued operations | $ — | $ 0.01 | $ 0.52 | $ (0.04) |
| Attributable to common stockholders | $ (0.01) | $ — | $ 0.47 | $ (0.07) |
| Weighted average shares outstanding (diluted) | 162,006,646 | 155,481,278 | 165,914,473 | 155,390,911 |

See accompanying notes to consolidated financial statements.

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**
**Consolidated Statements of Comprehensive Income (Loss)**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| Net income (loss) | $ (1,389,488) | $ (59,536) | $ 79,004,006 | $ (10,427,092) |
| Unrealized loss on available-for-sale securities | (172) | — | (1,200) | — |
| Comprehensive income (loss) | $ (1,389,660) | $ (59,536) | $ 79,002,806 | $ (10,427,092) |

See accompanying notes to consolidated financial statements.

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**
**Consolidated Statement of Stockholders' Equity (Deficit)**
**(unaudited)**

| | Common Stock | | Additional Paid-In | Accumulated | Accumulated Other Comprehensive | Non-controlling | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Loss | Interest | (Deficit) |
| Balance, December 31, 2016 | 155,762,729 | $ 155,763 | $326,564,148 | $(394,855,034) | $ — | $ 468,910 | $ (67,666,213) |
| Issued stock in payment of Board retainers | 16,406 | 17 | 10,483 | — | — | — | 10,500 |
| Issued stock in payment of employee bonuses | 710,353 | 710 | 368,632 | — | — | — | 369,342 |
| Issued stock upon exercise of warrants | 5,411,850 | 5,412 | 48,707 | — | — | — | 54,119 |
| Issued warrants in connection with Asset Sale | — | — | 3,337,187 | — | — | — | 3,337,187 |
| Issued warrants for extension of license agreement | — | — | 333,719 | — | — | — | 333,719 |
| Issued stock to 401(k) plan | 105,308 | 105 | 53,602 | — | — | — | 53,707 |
| Issued restricted stock | 200,000 | 200 | — | — | — | — | 200 |
| Stock compensation expense | — | — | 319,807 | — | — | — | 319,807 |
| Comprehensive income (loss) | | | | | | | |
| Net income | — | — | — | 79,004,198 | | (192) | 79,004,006 |
| Unrealized loss on available-for-sale securities | — | — | — | — | (1,200) | — | (1,200) |
| Total comprehensive income | — | — | — | — | — | — | 79,002,806 |
| Reclassification of funds invested (see Note 8) | — | — | — | — | — | 200,000 | 200,000 |
| Balance, September 30, 2017 | 162,206,646 | $ 162,207 | $331,036,285 | $(315,850,836) | $ (1,200) | $ 668,718 | $ 16,015,174 |

See accompanying notes to consolidated financial statements.

**Navidea Biopharmaceuticals, Inc. and Subsidiaries**
**Consolidated Statements of Cash Flows**
**(unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2017** | **2016** |
| Cash flows from operating activities: | | |
| Net income (loss) | $ 79,004,006 | $ (10,427,092) |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: | | |
| Depreciation and amortization | 212,077 | 378,834 |
| Loss on disposal and abandonment of assets | 806,710 | 136,719 |
| Gain on forgiveness of accounts payable | — | (85,355) |
| Change in inventory reserve | — | 43,354 |
| Amortization of debt discount and issuance costs | — | 77,964 |
| Debt discount and issuance costs written off | — | 1,955,541 |
| Prepayment premium and debt collection fees related to long term debt | — | 2,923,271 |
| Compounded interest on long term debt | 211,443 | 1,367,259 |
| Stock compensation expense | 319,807 | 310,642 |
| Loss on disposal of investment in R-NAV, LLC | — | 39,732 |
| Change in fair value of financial instruments | (153,357) | (1,755,989) |
| Issued warrants in connection with Asset Sale | 3,337,187 | — |
| Value of stock issued to directors | 10,500 | 56,609 |
| Value of stock issued to employees | 369,342 | — |
| Value of stock issued to 401(k) plan for employer matching contributions | 53,707 | 120,800 |
| Other | 65 | — |
| Changes in operating assets and liabilities: | | |
| Accounts and other receivables | (12,686,071) | 210,536 |
| Inventory | 1,470,826 | (195,330) |
| Prepaid expenses and other assets | 495,434 | 11,465 |
| Accounts payable | (5,897,416) | 3,212,632 |
| Accrued and other liabilities | (5,507,487) | 4,113,403 |
| Deferred revenue | (2,315,037) | (1,195,911) |
| Net cash provided by operating activities | 59,731,736 | 1,299,084 |
| Cash flows from investing activities: | | |
| Purchases of available-for-sale securities | (2,200,000) | — |
| Maturities of available-for-sale securities | 200,000 | — |
| Purchases of equipment | (31,417) | (1,847) |
| Proceeds from sales of equipment | — | 45,000 |
| Payments on disposal of investment in R-NAV, LLC | — | (110,000) |
| Proceeds from disposal of investment in R-NAV, LLC | — | 27,623 |
| Net cash used in investing activities | (2,031,417) | (39,224) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock | 54,319 | 140 |
| Payment of debt-related costs | — | (3,923,271) |
| Principal payments on notes payable | (59,675,502) | (189,163) |
| Release of restricted cash held for payment against debt | 5,001,188 | (3,501,247) |
| Payments under capital leases | — | (2,154) |
| Net cash used in financing activities | (54,619,995) | (7,615,695) |
| Net increase (decrease) in cash | 3,080,324 | (6,355,835) |
| Cash, beginning of period | 1,539,325 | 7,166,260 |
| Cash, end of period | $ 4,619,649 | $ 810,425 |

See accompanying notes to consolidated financial statements.

**Notes to the Consolidated Financial Statements (unaudited)**

**1. Summary of Significant Accounting Policies**

**a. Basis of Presentation:** The information presented as of September 30, 2017 and for the three-month and nine-month periods ended September 30, 2017 and 2016 is unaudited, but includes all adjustments (which consist only of normal recurring adjustments) that the management of Navidea Biopharmaceuticals, Inc. ("Navidea," the "Company," or "we") believes to be necessary for the fair presentation of results for the periods presented. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. The balances as of September 30, 2017 and the results for the interim periods are not necessarily indicative of results to be expected for the year. The consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2016, which were included as part of our Annual Report on Form 10-K.

Our consolidated financial statements include the accounts of Navidea and our wholly owned subsidiaries, Navidea Biopharmaceuticals Limited and Cardiosonix Ltd, as well as those of our majority-owned subsidiary, Macrophage Therapeutics, Inc. ("MT"). All significant inter-company accounts were eliminated in consolidation. Cardiosonix was legally dissolved in September 2017. Prior to termination of Navidea's joint venture with R-NAV, LLC ("R-NAV") in May 2016, Navidea's investment in R-NAV was being accounted for using the equity method of accounting and was therefore not consolidated.

On March 3, 2017, pursuant to an Asset Purchase Agreement dated November 23, 2016, (the "Purchase Agreement"), the Company completed its previously announced sale to Cardinal Health 414, LLC ("Cardinal Health 414") of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the "Business"), including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration ("FDA") and similar indications approved by the FDA in the future (the "Product"), in Canada, Mexico and the United States (the "Territory") (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the "Asset Sale"). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all rights, title and interest in and to the Product, as specified in the Purchase Agreement (the "Acquired Assets").

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the "Supply and Distribution Agreement"), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination).

Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Business as a discontinued operation. Cash flows associated with the operation of the Business have been combined with operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows. See Note 3.

**b. Financial Instruments and Fair Value:** In accordance with current accounting standards, the fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value, giving the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

*Level 1* – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

*Level 2* – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

*Level 3* – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 4.

The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

(1) Cash, restricted cash, available-for-sale securities, accounts and other receivables, and accounts payable: The carrying amounts approximate fair value because of the short maturity of these instruments.

(2) Notes payable: At September 30, 2017 and December 31, 2016, the conversion option of certain notes payable was required to be recorded at fair value. The estimated fair value of the conversion option was calculated using a Monte Carlo simulation. This valuation method includes Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. Unrealized gains and losses on the fair value of the conversion option are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations. At September 30, 2017, the fair value of the conversion option is approximately zero. See Note 10.

(3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling $63,000 as of September 30, 2017 and December 31, 2016 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of September 30, 2017 and December 31, 2016 included volatility, a risk-free rate and expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. See Note 4.

(4) Warrants: In March 2017, in connection with the Asset Sale, the Company granted to each of Cardinal Health 414 and the University of California, San Diego, ("UCSD"), a five-year warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company's common stock at an exercise price of $1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions (the "Series NN warrants"). The assumptions used to calculate fair value at the date of issuance included volatility, a risk-free rate and expected dividends. The Series NN warrants granted to Cardinal Health 414 had an estimated fair value of $3.3 million, which was recorded as a reduction of the gain on sale in the consolidated statement of operations for the three-month period ended March 31, 2017. The Series NN warrants granted to UCSD had an estimated fair value of $334,000, which was recorded as an intangible asset related to the UCSD license in the consolidated balance sheet during the three-month period ended March 31, 2017. See Note 14.

**c. Revenue Recognition:** We currently generate revenue primarily from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due.

We also earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. We received a non-refundable upfront cash payment of $2.0 million from SpePharm AG upon execution of the SpePharm License Agreement in March 2015. We determined that the license and other non-contingent deliverables did not have stand-alone value because the license could not be deemed to be fully delivered for its intended purpose unless we performed our other obligations, including specified development work. Accordingly, they did not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment was deferred and was being recognized on a straight-line basis over the estimated obligation period of two years. However, the remaining deferred revenue of $417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, several months earlier than originally anticipated.

**d. Recently Adopted Accounting Standards:** In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation – Stock Compensation (Topic 178): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for public business entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Methods of adoption vary according to each of the amendment provisions. The adoption of ASU 2016-09 on January 1, 2017 did not have a material impact on the Company's financial statements because:

- As of December 31, 2016, $15.3 million of our U.S. net operating loss carryforwards related to stock-based compensation tax deductions in excess of book compensation expense ("APIC NOLs"), that will be credited to additional paid-in capital when such deductions reduce taxes payable as determined on a "with-and-without" basis. Accordingly, these APIC NOLs will reduce federal taxes payable if realized in future periods. As of December 31, 2016, we have also recorded a full valuation allowance against these APIC NOLs. This resulted in a zero cumulative effect adjustment to accumulated deficit as a result of the adoption of ASU 2016-09.

- Due to the full valuation allowance for the Company's tax provision, these APIC NOLs have never been recorded in additional paid-in-capital. The Company does not anticipate any impact going forward, as any amounts to be recorded in the consolidated statements of operations would be fully offset by the valuation allowance, nor would they result in a related classification in cash flows for operating activities.

- The Company will continue to recognize forfeitures through estimates consistent with our past practices as opposed to when they occur.

- The Company already classifies cash paid to taxing authorities arising from the withholding of shares from employees in cash flows from financing activities.

**e.** **Recent Accounting Standards:** In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will supersede existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is that a company should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process that requires companies to exercise more judgment and make more estimates than under the current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. Since the issuance of ASU 2014-09, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. ASU 2014-09 allows a choice of transition methods: (a) a full retrospective adoption in which the standard is applied to all of the periods presented, or (b) a modified retrospective adoption in which the standard is applied only to the most current period presented in the financial statements with a cumulative-effect adjustment reflected in retained earnings. ASU 2014-09 also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity's nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those periods.

Following the sale of the Business to Cardinal Health 414 in March 2017, we generate revenue primarily from grants to support certain of our product development programs. Such grant revenues are recognized only after expenses reimbursable under the grants have been paid. We also earn revenues related to our licensing and distribution agreements. The consideration we are eligible to receive under our licensing and distribution agreements typically includes upfront payments, reimbursement for research and development costs, milestone payments, and royalties. Each licensing and distribution agreement is unique and will require separate assessment using the five-step process under ASU 2014-09. Management is working to complete its evaluation of the impact of adopting ASU 2014-09, however we currently do not anticipate that it will have a material effect on our consolidated financial statements. We will adopt ASU 2014-09 along with additional related ASUs effective January 1, 2018. We currently plan to use the modified retrospective method of adoption.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic *805), Clarifying the Definition of a Business*. ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a "set") is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. Management is currently evaluating the impact that the adoption of ASU 2017-01 will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all of the following criteria are met: (1) The fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. Disclosure requirements remain unchanged. ASU 2017-09 is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted as described in ASU 2017-09. Management is currently evaluating the impact that the adoption of ASU 2017-09 will have on our consolidated financial statements.

In September 2017, the FASB issued ASU No. 2017-13, *Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842)*. ASU 2017-13 adds SEC paragraphs pursuant to an SEC Staff Announcement made in July 2017 and clarifies several issues related to transition and implementation of the covered topics, including clarification of the definition of a public business entity, the effect of a change in tax law or rates on leveraged leases, and related amendments to the eXstensible Business Reporting Language ("XBRL") taxonomy. Management is currently evaluating the impact that the adoption of ASU 2017-13 will have on our consolidated financial statements.

## 2. Liquidity

Prior to the Asset Sale to Cardinal Health 414 in March 2017, all of our material assets were pledged as collateral for our borrowings under our Term Loan Agreement with Capital Royalty Partners II L.P. and certain of its affiliates (collectively, "CRG") (the "CRG Loan Agreement"). In addition to the security interest in our assets, the CRG Loan Agreement included covenants that imposed significant requirements on us. An event of default would have entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to CRG under the loan agreement and the related security agreement. During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of $4.1 million that was on deposit.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid $59 million (the "Deposit Amount") of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the "Final Payoff Amount"). The Company and CRG further agreed that the Final Payoff Amount would be no less than $47 million (the "Low Payoff Amount") and no more than $66 million (the "High Payoff Amount"). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a $7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a $12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of $59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The $2 million being held in escrow pursuant to court order in the Ohio case and the $3 million being held in escrow pursuant to court order in the Texas case were released to the Company following the closing of the Asset Sale.

In addition, the Company previously was a party to a Loan Agreement with Platinum-Montaur Life Sciences LLC ("Platinum-Montaur"), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, "Platinum") (the "Platinum Loan Agreement") and a Third Amended and Restated Promissory Note ("Platinum Note") given by Navidea in favor of Platinum-Montaur.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to Platinum Partners Credit Opportunities Master Fund, LP ("PPCO") an aggregate of approximately $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which was purportedly transferred by Platinum-Montaur to PPCO. The Company was informed by Platinum Partners Value Arbitrage Fund LP ("PPVA") that it was the owner of the balance of the Platinum Note. Such balance of approximately $1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

On March 2, 2017, PPCO provided a payoff letter (the "Payoff Letter"). In the Payoff Letter, PPCO defined "Indebtedness" to include all amounts due under the Platinum Note, indicated that upon payment of the Payoff Amount, all "Indebtedness owed to Lender" shall have been satisfied in full, and that the "Loan Documents," which included the Platinum Loan Agreement and the Platinum Note, "shall terminate and have no further force or effect." The letter also confirmed that as of the date that payment was made by Navidea, the Receiver was providing a release and indemnification in favor of Navidea based on any claims made by any affiliate of PPCO. The Payoff Amount was paid pursuant to the Payoff Letter.

The remaining balance of the Platinum Note would have matured under its terms in September 2017, however the Company has not paid the balance as it is still subject to ongoing competing claims of ownership. The Company intends to pay the balance of the debt if it is determined to be due and owing to PPVA or Dr. Goldberg.

Based on our current working capital and our projected cash burn, including the potential for the Company to pay up to an additional $7 million to CRG depending upon the outcome of the Texas litigation, management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q. Our projected cash burn also factors in certain cost cutting initiatives that have been implemented and approved by the board of directors, including reductions in the workforce and a reduction in facilities expenses. Additionally, we have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. We believe all of these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern.

**3. Discontinued Operations**

On March 3, 2017, the Company completed the sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer, including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the FDA and similar indications approved by the FDA in the future, in Canada, Mexico and the United States.

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately $80.6 million after adjustments based on inventory being transferred and an advance of $3 million of guaranteed earnout payments as part of the CRG settlement, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed $230 million over a period of ten years, of which $20.1 million are guaranteed payments of $6.7 million per year for each of the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, $3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG. This advance is to be applied to the third year of guaranteed payments.

We recorded a net gain on the sale of the Business of $86.9 million for the nine months ended September 30, 2017, including $16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by $3.3 million in estimated fair value of warrants issued to Cardinal Health 414, $2.0 million in legal and other fees related to the sale, $800,000 in net balance sheet dispositions and write-offs, and $6.4 million in estimated taxes.

As a result of the Asset Sale, we reclassified certain assets and liabilities as assets and liabilities associated with discontinued operations. The following assets and liabilities have been segregated and included in assets associated with discontinued operations or liabilities associated with discontinued operations, as appropriate, in the consolidated balance sheets:

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Accounts and other receivables | $ — | $ 1,598,994 |
| Inventory, net | — | 1,374,618 |
| Prepaid expenses | — | 170,635 |
| Assets associated with discontinued operations, current | — | 3,144,247 |
| Property and equipment, net of accumulated depreciation | — | 70,973 |
| Patents and trademarks, net of accumulated amortization | — | 34,282 |
| Assets associated with discontinued operations, noncurrent | — | 105,255 |
| Total assets associated with discontinued operations | $ — | $ 3,249,502 |
| | | |
| Accounts payable | $ 232 | $ 1,957,938 |
| Accrued liabilities | 32,909 | 607,659 |
| Deferred revenue | — | 2,300,000 |
| Liabilities associated with discontinued operations, current | $ 33,141 | $ 4,865,597 |

In addition, we reclassified certain revenues and expenses related to the Business to discontinued operations for all periods presented, including interest expense related to the CRG and Platinum debt obligations as required by current accounting guidance. The following amounts have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Revenue: | | | | |
| Lymphoseek sales revenue | $ — | $ 6,672,489 | $ 2,917,213 | $ 14,673,689 |
| Grant and other revenue | — | 385 | — | 575 |
| Total revenue | — | 6,672,874 | 2,917,213 | 14,674,264 |
| Cost of goods sold | — | 918,928 | 364,192 | 2,012,301 |
| Gross profit | — | 5,753,946 | 2,553,021 | 12,661,963 |
| Operating expenses: | | | | |
| Research and development | (5,951) | 356,612 | 382,070 | 1,450,231 |
| Selling, general and administrative | — | 1,129,093 | 805,464 | 4,092,951 |
| Total operating expenses | (5,951) | 1,485,705 | 1,187,534 | 5,543,182 |
| Income from discontinued operations | 5,951 | 4,268,241 | 1,365,487 | 7,118,781 |
| Interest expense | — | (2,566,330) | (1,718,506) | (12,286,093) |
| Income (loss) before income taxes | 5,951 | 1,701,911 | (353,019) | (5,167,312) |
| Benefit from (provision for) income taxes | (552) | — | 20,181 | — |
| Income (loss) from discontinued operations | $ 5,399 | $ 1,701,911 | $ (332,838) | $ (5,167,312) |

## 4. Fair Value

The Company has been informed by PPVA that it is the owner of the balance of the Platinum Note. Such balance of approximately $1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone because it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA. The remaining balance of the Platinum Note would have matured under its terms in September 2017, however the Company has not paid the balance as it is still subject to ongoing competing claims of ownership. The Company intends to pay the balance of the debt if it is determined to be due and owing to PPVA or Dr. Goldberg.

If determined to be the obligee under the Platinum Note, Platinum or Dr. Goldberg would have had the right to convert all or any portion of the unpaid principal or unpaid interest accrued on all draws under the Platinum credit facility, under certain circumstances. The Platinum embedded option to convert such debt into common stock is recorded at fair value on the consolidated balance sheets and deemed to be a derivative instrument as the amount of shares to be issued upon conversion is indeterminable. The estimated fair value of the conversion option of the Platinum Note payable is approximately $0 and $153,000 on September 30, 2017 and December 31, 2016, respectively. Subsequent to its maturity in September 2017, the Platinum Note no longer has an embedded conversion option.

MT issued warrants to purchase MT Common Stock with certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value on the consolidated balance sheets. The estimated fair value of the MT warrants is $63,000 at both September 30, 2017 and December 31, 2016, and will continue to be measured on a recurring basis. See Note 1(b)(3).

The following tables set forth, by level, financial liabilities measured at fair value on a recurring basis:

**Liabilities Measured at Fair Value on a Recurring Basis as of September 30, 2017**

| Description | Quoted Prices in Active Markets for Identical Liabilities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|---|---|---|---|---|
| Platinum conversion option | $ — | $ — | $ — | $ — |
| Liability related to MT warrants | — | — | 63,000 | 63,000 |

**Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2016**

| Description | Quoted Prices in Active Markets for Identical Liabilities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|---|---|---|---|---|
| Platinum conversion option | $ — | $ — | $ 153,357 | $ 153,357 |
| Liability related to MT warrants | — | — | 63,000 | 63,000 |

**a. Valuation Processes-Level 3 Measurements:** The Company utilizes third-party valuation services that use complex models such as Monte Carlo simulation to estimate the value of our financial liabilities. Each reporting period, the Company provides significant unobservable inputs to the third-party valuation experts based on current internal estimates and forecasts.

The assumptions used in the Monte Carlo simulation as of September 30, 2017 and December 31, 2016 are summarized in the following table:

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Estimated volatility | 0% | 76% |
| Expected term (in years) | 0 | 4.75 |
| Debt rate | 8.125% | 8.125% |
| Beginning stock price | $ 0.42 | $ 0.64 |

**b. Sensitivity Analysis-Level 3 Measurements:** Changes in the Company's current internal estimates and forecasts were likely to cause material changes in the fair value of the Platinum conversion option. The significant unobservable inputs used in the fair value measurement of the liability included the amount and timing of future draws expected to be taken under the Platinum Loan Agreement based on then-current internal forecasts and management's estimate of the likelihood of actually making those draws as opposed to obtaining other sources of financing. Significant increases (decreases) in any of the significant unobservable inputs would result in a higher (lower) fair value measurement. A change in one of the inputs would not necessarily result in a directionally similar change in the others.

There were no Level 1 or Level 2 liabilities outstanding at any time during the three-month and nine-month periods ended September 30, 2017 and 2016. There were no transfers in or out of our Level 1 or Level 2 liabilities during the three-month and nine-month periods ended September 30, 2017 or 2016. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses) are recorded as changes in fair value of financial instruments in the consolidated statements of operations. The change in the estimated fair value of our Level 3 liabilities during the three-month periods ended September 30, 2017 and 2016 was $0 and an increase of $839,000, respectively. The change in the estimated fair value of our Level 3 liabilities during the nine-month periods ended September 30, 2017 and 2016 was decreases of $153,000 and $1.8 million, respectively.

## 5. Stock-Based Compensation

For the three-month periods ended September 30, 2017 and 2016, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $64,000 and $50,000, respectively. For the nine-month periods ended September 30, 2017 and 2016, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $320,000 and $311,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or nine-month periods ended September 30, 2017 and 2016.

A summary of the status of our stock options as of September 30, 2017, and changes during the nine-month period then ended, is presented below:

| | Nine Months Ended September 30, 2017 | | | |
|---|---|---|---|---|
| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value |
| Outstanding at beginning of period | 3,380,615 | $ 2.00 | | |
| Granted | 1,390,000 | 0.75 | | |
| Exercised | — | — | | |
| Canceled and Forfeited | (756,601) | 1.64 | | |
| Expired | — | — | | |
| Outstanding at end of period | 4,014,014 | $ 1.63 | 6.6 | $ 2,650 |
| Exercisable at end of period | 2,519,780 | $ 2.11 | 4.9 | $ 2,650 |

A summary of the status of our unvested restricted stock as of September 30, 2017, and changes during the nine-month period then ended, is presented below:

| | Nine Months Ended September 30, 2017 | |
|---|---|---|
| | Number of Shares | Weighted Average Grant-Date Fair Value |
| Unvested at beginning of period | 207,000 | $ 1.17 |
| Granted | 200,000 | 0.51 |
| Vested | (207,000) | 1.17 |
| Forfeited | — | — |
| Unvested at end of period | 200,000 | $ 0.51 |

As of September 30, 2017, there was approximately $181,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of approximately 1 year.

## 6. Earnings (Loss) Per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares and, except for periods with a loss from operations, participating securities outstanding during the period. Diluted earnings (loss) per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible debt, convertible preferred stock, options and warrants.

The following table sets forth the reconciliation of the weighted average number of common shares outstanding used to compute basic and diluted earnings (loss) per share for the three-month and nine-month periods ended September 30, 2017 and 2016:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Weighted average shares outstanding, basic | 162,006,646 | 155,481,278 | 161,437,276 | 155,390,911 |
| Dilutive shares related to warrants | — | — | 4,277,197 | — |
| Unvested restricted stock | — | — | 200,000 | — |
| Weighted average shares outstanding, diluted | 162,006,646 | 155,481,278 | 165,914,473 | 155,390,911 |

Diluted earnings (loss) per common share for the nine-month periods ended September 30, 2017 and 2016 excludes the effects of 15.1 million and 14.5 million common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

The Company's unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as "participating securities"). Therefore, the unvested stock awards are required to be included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 200,000 and 257,000 shares of unvested restricted stock for the nine-month periods ended September 30, 2017 and 2016, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

## 7. Inventory

All components of inventory are valued at the lower of cost (first-in, first-out) or net realizable value. We adjust inventory to net realizable value if the net realizable value is lower than the carrying cost of the inventory. Net realizable value is determined based on estimated sales activity and margins. We estimate a reserve for obsolete inventory based on management's judgment of probable future commercial use, which is based on an analysis of current inventory levels, estimated future sales and production rates, and estimated shelf lives.

The components of inventory as of September 30, 2017 and December 31, 2016 are as follows:

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| | (unaudited) | |
| Materials | $ — | $ 94,500 |
| Work-in-process | — | 1,708 |
| Finished goods | 748 | — |
| Reserves | (748) | — |
| Total | $ — | $ 96,208 |

## 8. Investment in Macrophage Therapeutics, Inc.

In March 2015, Platinum and Dr. Goldberg (collectively, the "MT Investors") invested $300,000 and $200,000, respectively, in MT in exchange for shares of MT's Series A Convertible Preferred Stock ("MT Preferred Stock") and warrants to purchase common shares of MT ("MT Common Stock"). The MT Preferred Stock and warrants are convertible into, and exercisable for, MT Common Stock.

In December 2015 and May 2016, Platinum made additional investments in MT totaling $200,000. MT was not obligated to provide anything in return, although it was considered likely that the MT Board of Directors would ultimately authorize some form of compensation to Platinum. During the year ended December 31, 2016, the Company recorded the entire additional $200,000 investment as a current liability pending determination of the form of compensation.

In 2016, MT's Board of Directors authorized modification of the original MT Preferred Stock to a convertible preferred stock with a 10% paid-in-kind ("PIK") coupon retroactive to the time the initial investments were made. The conversion price of the MT Preferred Stock will remain at the $500 million initial market cap but a full ratchet was added to enable the adjustment of conversion price, warrant number and exercise price based on the valuation of the first institutional investment round. In addition, the MT Board of Directors authorized issuance of additional MT Preferred Stock with the same terms to Platinum as compensation for the additional $200,000 of investments made in December 2015 and May 2016. Based on the decision to issue equity for the additional $200,000 of investments made by Platinum, the liability was reclassified to additional paid-in-capital in January 2017. As of the date of filing of this Quarterly Report on Form 10-Q, final documents related to the above transactions authorized by the MT Board have not been completed.

## 9. Accounts Payable, Accrued Liabilities and Other

Accounts payable at September 30, 2017 and December 31, 2016 includes an aggregate of $0 and $116,000, respectively, due to related parties related to director fees and MT scientific advisory board fees. At September 30, 2017, approximately $96,000 of accounts payable is being disputed by the Company related to legal fees associated with unauthorized expenditures by a former executive, which were incurred during the year ended December 31, 2016.

Accrued liabilities and other at September 30, 2017 includes $64,000 due to related parties for director fees. Accrued liabilities and other at December 31, 2016 includes an aggregate of $106,000 due to related parties for executive bonuses, director fees, deferred salary owed to Dr. Goldberg, and MT scientific advisory board fees.

## 10. Notes Payable

*Platinum*

In July 2012, we entered into an agreement with Platinum-Montaur to provide us with a credit facility of up to $50 million. In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement, which was purportedly transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum Note. Such balance of approximately $1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA. The remaining balance of the Platinum Note would have matured under its terms in September 2017, however the Company has not paid the balance as it is still subject to ongoing competing claims of ownership. The Company intends to pay the balance of the debt if it is determined to be due and owing to PPVA or Dr. Goldberg.

During the nine-month periods ended September 30, 2017 and 2016, $211,000 and $814,000 of interest was compounded and added to the balance of the Platinum Note, respectively. As of September 30, 2017, the remaining outstanding principal balance of the Platinum Note was approximately $2.0 million.

Until such time as there is a legal determination regarding liability under the Platinum Note, it is reflected as a liability on the consolidated balance sheets at its unpaid principal and interest balance of $1,981,676 and $9,487,822 at September 30, 2017 and December 31, 2016, respectively. Additionally, the estimated fair value of the embedded conversion option of approximately $0 and $153,000 at September 30, 2017 and December 31, 2016, respectively, is included in notes payable on the consolidated balance sheets. Changes in the estimated fair value of the Platinum conversion option were $0 and an increase of $839,000, respectively, and were recorded as non-cash changes in fair value of the conversion option during the three-month periods ended September 30, 2017 and 2016. Changes in the estimated fair value of the Platinum conversion option were decreases of $153,000 and $1.8 million, respectively, and were recorded as non-cash changes in fair value of the conversion option during the nine-month periods ended September 30, 2017 and 2016.

*Capital Royalty Partners II, L.P.*

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement (the "CRG Loan Agreement") with Capital Royalty Partners II L.P. ("CRG") in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the "Lenders") in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50 million (the "CRG Term Loan"), with an additional $10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. During the three-month period ended March 31, 2016, $519,000 of interest was compounded and added to the balance of the CRG Term Loan.

Pursuant to a notice of default letter sent to Navidea by CRG in April 2016, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest. As of December 31, 2016, $5.8 million of accrued interest related to the CRG Term Loan is included in accrued liabilities and other on the consolidated balance sheets. As of December 31, 2016, the outstanding principal balance of the CRG Term Loan was $51.7 million.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of $4.1 million that was on deposit.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid $59 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents. The Company and CRG further agreed that the Final Payoff Amount would be no less than $47 million and no more than $66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a $7 million letter of credit in favor of CRG as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a $12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of $59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement.

*IPFS Corporation*

In December 2016, we prepaid $348,000 of insurance premiums through the issuance of a note payable to IPFS Corporation ("IPFS") with an interest rate of 8.99%. The note was payable in eight monthly installments of $45,000, with the final payment due on July 10, 2017. As of September 30, 2017 and December 31, 2016, the remaining outstanding principal balance of the IPFS note payable is approximately $0 and $306,000, respectively, and is included in notes payable, current in the consolidated balance sheets.

*Summary*

During the three-month periods ended September 30, 2017 and 2016, we recorded interest expense of $26,000 and $2.6 million, respectively, related to our notes payable. Of these amounts, $29,000 and $190,000, respectively, was compounded and added to the balance of our notes payable during the three-month periods ended September 30, 2017 and 2016, respectively. During the nine-month periods ended September 30, 2017 and 2016, we recorded interest expense of $1.8 million and $12.3 million, respectively, related to our notes payable. Of these amounts, $0 and $78,000, respectively, related to amortization of the debt discounts related to our notes payable. An additional $211,000 and $1.4 million of total interest expense was compounded and added to the balance of our notes payable during the nine-month periods ended September 30, 2017 and 2016, respectively. The collection fees of $778,000, prepayment premium of $2.1 million, and the remaining unamortized balance of the CRG debt discount of $2.0 million were also recorded as interest expense during the nine-month period ended September 30, 2016.

## 11. Terminated Lease Liability

Effective June 1, 2017, Navidea relocated its Dublin, Ohio headquarters from 5600 Blazer Parkway ("Blazer") to a smaller space at 4995 Bradenton Avenue. The Company concurrently executed a sublease arrangement ("Sublease") for the Blazer space because there is no early termination provision in the Blazer lease. The Blazer lease and the Sublease end simultaneously in October 2022.

In accordance with current accounting guidance, the Company recorded a total liability of $1.0 million, which is equal to the fair value of the remaining payments due under the Blazer Lease, net of the fair value of the payments to be received by the Company under the Sublease, and including a finder's fee. The Company also recorded a loss on contract termination of $429,000 and a loss on disposal of assets, primarily leasehold improvements and furniture and fixtures, related to the Blazer space of $706,000. Both losses are included in selling, general and administrative expenses for the nine-month periods ended September 30, 2017.

A summary of the changes in our terminated lease liability during the nine-month period ended September 30, 2017 is presented below:

| | Terminated Lease Liability |
|---|---|
| Total liability, June 1, 2017 (date of sublease) | $ 943,675 |
| Additional finder's fees required by contract | 80,371 |
| Payment of finder's fees | (152,584) |
| Payments under Blazer lease | (188,847) |
| Receipts from subtenant | 78,248 |
| Accretion of liability | 12,813 |
| Total liability, September 30, 2017 | $ 773,676 |

## 12. Commitments and Contingencies

We are subject to legal proceedings and claims that arise in the ordinary course of business.

*Sinotau Litigation – NAV4694*

On August 31, 2015, Hainan Sinotau Pharmaceutical Co., Ltd. ("Sinotau") filed a suit for damages, specific performance, and injunctive relief against the Company in the U.S. District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company's NAV4694 product candidate and technology (the "Sinotau Litigation"). In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and on July 20, 2017, the parties filed a joint motion to stay the case for 60 days pending settlement discussion. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau Technologies, Inc. ("Cerveau"), outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims.

*CRG Litigation*

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of $4.1 million that was on deposit, applying $3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining $189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the $59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than $47 million and no more than $66 million. In addition, CRG agreed that Navidea had the right to assert all affirmative defenses to its claim of default. In the underlying case the district court had entered summary judgment in favor of CRG finding unspecified events of default but refusing to consider affirmative defenses raised by Navidea as not before the Court. Subsequent to the settlement CRG moved again for entry of judgment in its favor; Navidea objected that the Settlement Agreement specifically allowed it to raise affirmative defenses and the district court agreed with Navidea setting the case for trial in December 2017. CRG once again moved for summary judgment and the motion was heard by the Court on October 30, 2017. The Court did not indicate when it intends to rule on the motion. The trial is currently scheduled for December 11, 2017.

Concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a $7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a $12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of $59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant

exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The $2 million being held in escrow pursuant to court order in the Ohio case and the $3 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. See Notes 2 and 10.

*Former CEO Arbitration*

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to certain provisions in his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez was seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In response, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez withdrew his claim for additional severance pursuant to his Employment Agreement, and the Company withdrew its counterclaims. On May 12, 2017, the Company received a ruling in favor of Mr. Gonzalez finding that he was terminated by the Company without cause on April 7, 2016. Mr. Gonzalez was awarded salary, bonus, and benefits in the aggregate amount of $481,039 plus interest, attorneys' fees, and other costs. The arbitration award is final and binding on the parties. The Company paid an aggregate of $617,880 to Mr. Gonzalez on May 16, 2017.

*FTI Consulting, Inc. Litigation*

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of $782,600 comprised of: (i) $730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement between FTI and the Company, and (ii) in excess of $52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. On June 26, 2017, the Company and FTI entered into a settlement agreement. According to FTI, as of June 2017, FTI was owed $862,165 including interest charges and legal fees. Under the terms of the settlement agreement, the Company paid an aggregate of $435,000 to FTI on June 30, 2017.

*Sinotau Litigation – Tc99m Tilmanocept*

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On July 12, 2017, the District of Delaware case was transferred to the Southern District of Ohio. On July 27, 2017 the Ohio Court determined that both cases in the Southern District of Ohio are related and the case was stayed for 60 days pending settlement discussions. Both cases remain open because all issues raised in the complaints have not been resolved but the parties have continued settlement discussions and the Court extended the stays in both cases.

*Platinum-Montaur Life Sciences LLC*

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of $1,914,827 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement (discussed above). The Company has not yet been served with process in the action. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

In accordance with ASC Topic 450, *Contingencies*, we make a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the case of the CRG litigation, we could still be required to pay up to an additional $7 million to CRG depending upon the outcome of the Texas litigation, which would have a material negative impact on our financial position. Although the outcome of any litigation is uncertain, in our opinion, the amount of ultimate liability, if any, with respect to any of these actions other than CRG will not materially affect our financial position.

## 13. Equity Instruments

During the nine-month periods ended September 30, 2017 and 2016, we issued 16,406 and 72,649 shares of our common stock valued at approximately $10,500 and $56,609 to certain members of our Board of Directors as payment in lieu of cash for their retainer fees.

Also during the nine-month period ended September 30, 2017, we issued 710,353 shares of our common stock valued at $369,342 to our employees as partial payment in lieu of cash for their 2015 and 2016 bonuses.

## 14. Stock Warrants

In January 2017, Dr. Michael Goldberg, the Company's President and CEO, exercised 5,411,850 of his Series LL warrants in exchange for 5,411,850 shares of our common stock, resulting in proceeds to the Company of $54,119.

In March 2017, in connection with the Asset Sale, the Company granted to each of Cardinal Health 414 and UCSD, a five-year warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company's common stock at an exercise price of $1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions (the "Series NN warrants"). The fair value of the Series NN warrants was calculated using the Black-Scholes model using our five-year historical weekly volatility of 77% and a risk-free rate equal to the five-year treasury constant maturity rate of 2%. The Series NN warrants granted to Cardinal Health 414 had an estimated fair value of $3.3 million, which was recorded as a reduction of the gain on sale in the consolidated statement of operations for the three-month period ended March 31, 2017. The Series NN warrants granted to UCSD had an estimated fair value of $334,000, which was recorded as an intangible asset related to the UCSD license in the consolidated balance sheet during the three-month period ended March 31, 2017.

At September 30, 2017, there are 16.9 million warrants outstanding to purchase Navidea's common stock. The warrants are exercisable at prices ranging from $0.01 to $3.04 per share with a weighted average exercise price of $1.19 per share. The warrants have remaining outstanding terms ranging from 1 to 18 years.

In addition, at September 30, 2017, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at $2,000 per share.

## 15. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at September 30, 2017 and December 31, 2016.

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of September 30, 2017 or December 31, 2016 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of September 30, 2017, tax years 2013-2016 remained subject to examination by federal and state tax authorities.

Benefit from income taxes was $789,000 for the three-month period ended September 30, 2017, representing an effective tax rate of 34%, as compared to $0 for the three-month period ended September 30, 2016, representing an effective tax rate of 0%. The increase in the effective rate for the period ended September 30, 2017 compared with the same period in 2016 is primarily due to the gain on sale of our Lymphoseek product.

As of September 30, 2017, we had approximately $127.7 million of federal and $16.2 million of state net operating loss carryforwards.

**16. Segments**

We report information about our operating segments using the "management approach" in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, our R-NAV joint venture (terminated on May 31, 2016), NAV4694 and NAV5001 (license terminated in April 2015), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc.

The information in the following tables is derived directly from each reportable segment's financial reporting.

| Three Months Ended September 30, 2017 | Diagnostics | Therapeutics | Corporate | Total |
|---|---|---|---|---|
| Tc99m tilmanocept sales revenue: | | | | |
| United States | $ — | $ — | $ — | $ — |
| International | — | — | — | — |
| Tc99m tilmanocept license revenue | — | — | — | — |
| Grant and other revenue | 210,479 | 13,190 | — | 223,669 |
| Total revenue | 210,479 | 13,190 | — | 223,669 |
| Cost of goods sold, excluding depreciation and amortization | — | — | — | — |
| Research and development expenses, excluding depreciation and amortization | 734,539 | 140,008 | — | 874,547 |
| Selling, general and administrative expenses, excluding depreciation and amortization [1] | — | 13,359 | 1,671,022 | 1,684,381 |
| Depreciation and amortization [2] | — | — | 50,326 | 50,326 |
| Loss from operations [3] | (524,060) | (140,177) | (1,721,348) | (2,385,585) |
| Other income [4] | — | — | 69,071 | 69,071 |
| Income tax benefit | 175,496 | 46,942 | 553,312 | 775,750 |
| Net loss from continuing operations | (348,564) | (93,235) | (1,098,965) | (1,540,764) |
| Income from discontinued operations, net of tax | 5,399 | — | — | 5,399 |
| Gain on sale of discontinued operations, net of tax | 145,877 | — | — | 145,877 |
| Net loss | (197,288) | (93,235) | (1,098,965) | (1,389,488) |
| Total assets, net of depreciation and amortization: | | | | |
| United States | 14,675,489 | 10,591 | 7,835,426 | 22,521,506 |
| International | 82,334 | — | 1,867 | 84,201 |
| Capital expenditures | — | — | 23,247 | 23,247 |

| Three Months Ended September 30, 2016 | Diagnostics | Therapeutics | Corporate | Total |
|---|---|---|---|---|
| Tc99m tilmanocept sales revenue: | | | | |
| United States | $ — | $ — | $ — | $ — |
| International | 17,601 | — | — | 17,601 |
| Tc99m tilmanocept license revenue | 1,295,625 | — | — | 1,295,625 |
| Grant and other revenue | 500,628 | 10,346 | — | 510,974 |
| Total revenue | 1,813,854 | 10,346 | — | 1,824,200 |
| Cost of goods sold, excluding depreciation and amortization | 2,889 | — | — | 2,889 |
| Research and development expenses, excluding depreciation and amortization | 671,777 | 247,664 | — | 919,441 |
| Selling, general and administrative expenses, excluding depreciation and amortization [1] | — | 27,758 | 1,694,073 | 1,721,831 |
| Depreciation and amortization [2] | — | — | 89,849 | 89,849 |
| Income (loss) from operations [3] | 1,139,188 | (265,076) | (1,783,922) | (909,810) |
| Other expenses [4] | — | — | (851,637) | (851,637) |
| Net income (loss) from continuing operations | 1,139,188 | (265,076) | (2,635,559) | (1,761,447) |
| Income from discontinued operations, net of tax | 1,701,911 | — | — | 1,701,911 |
| Net income (loss) | 2,841,099 | (265,076) | (2,635,559) | (59,536) |
| Total assets, net of depreciation and amortization: | | | | |
| United States | 4,950,756 | 9,356 | 6,080,567 | 11,040,679 |
| International | 148,224 | — | 697 | 148,921 |
| Capital expenditures | — | — | — | — |

| Nine Months Ended September 30, 2017 | Diagnostics | Therapeutics | Corporate | Total |
|---|---|---|---|---|
| Tc99m tilmanocept sales revenue: | | | | |
| United States | $ — | $ — | $ — | $ — |
| International | — | — | — | — |
| Tc99m tilmanocept license revenue | 100,000 | — | — | 100,000 |
| Grant and other revenue | 1,200,216 | 115,082 | — | 1,315,298 |
| Total revenue | 1,300,216 | 115,082 | — | 1,415,298 |
| Cost of goods sold, excluding depreciation and amortization | — | — | — | — |
| Research and development expenses, excluding depreciation and amortization | 2,255,842 | 509,853 | — | 2,765,695 |
| Selling, general and administrative expenses, excluding depreciation and amortization [1] | — | 19,342 | 8,789,728 | 8,809,070 |
| Depreciation and amortization [2] | — | — | 197,655 | 197,655 |
| Loss from operations [3] | (955,626) | (414,113) | (8,987,383) | (10,357,122) |
| Other expenses [4] | — | — | (1,061,190) | (1,061,190) |
| Income tax benefit | 323,149 | 140,034 | 3,397,972 | 3,861,156 |
| Net loss from continuing operations | (632,477) | (274,079) | (6,650,601) | (7,557,156) |
| Loss from discontinued operations, net of tax | (332,838) | — | — | (332,838) |
| Gain on sale of discontinued operations, net of tax | 86,894,000 | — | — | 86,894,000 |
| Net income (loss) | 85,928,685 | (274,079) | (6,650,601) | 79,004,006 |
| Total assets, net of depreciation and amortization: | | | | |
| United States | 14,675,489 | 10,591 | 7,835,426 | 22,521,506 |
| International | 82,334 | — | 1,867 | 84,201 |
| Capital expenditures | — | — | 31,417 | 31,417 |

| Nine Months Ended September 30, 2016 | Diagnostics | Therapeutics | Corporate | Total |
|---|---|---|---|---|
| Tc99m tilmanocept sales revenue: | | | | |
| United States | $ — | $ — | $ — | $ — |
| International | 30,800 | — | — | 30,800 |
| Tc99m tilmanocept license revenue | 1,795,625 | — | — | 1,795,625 |
| Grant and other revenue | 2,051,622 | 61,798 | — | 2,113,420 |
| Total revenue | 3,878,047 | 61,798 | — | 3,939,845 |
| Cost of goods sold, excluding depreciation and amortization | 5,185 | — | — | 5,185 |
| Research and development expenses, excluding depreciation and amortization | 4,410,133 | 600,790 | — | 5,010,923 |
| Selling, general and administrative expenses, excluding depreciation and amortization [1] | — | 31,590 | 5,542,034 | 5,573,624 |
| Depreciation and amortization [2] | — | — | 258,999 | 258,999 |
| Loss from operations [3] | (537,271) | (570,582) | (5,801,033) | (6,908,886) |
| Other income, excluding equity in loss of R-NAV, LLC [4] | — | — | 1,664,265 | 1,664,265 |
| Equity in loss of R-NAV, LLC | — | — | (15,159) | (15,159) |
| Net loss from continuing operations | (537,271) | (570,582) | (4,151,927) | (5,259,780) |
| Loss from discontinued operations, net of tax | (5,167,312) | — | — | (5,167,312) |
| Net loss | (5,704,583) | (570,582) | (4,151,927) | (10,427,092) |
| Total assets, net of depreciation and amortization: | | | | |
| United States | 4,950,756 | 9,356 | 6,080,567 | 11,040,679 |
| International | 148,224 | — | 697 | 148,921 |
| Capital expenditures | — | — | 1,847 | 1,847 |

(1) General and administrative expenses, excluding depreciation and amortization, represent costs that relate to the general administration of the Company and as such are not currently allocated to our individual reportable segments.

(2) Depreciation and amortization is reflected in selling, general and administrative expenses ($50,326 and $89,849 for the three-month periods ended September 30, 2017 and 2016 and $197,655 and $258,999 for the nine-month periods ended September 30, 2017 and 2016, respectively).

(3) Income (loss) from operations does not reflect the allocation of certain selling, general and administrative expenses, excluding depreciation and amortization, to our individual reportable segments.

(4) Amounts consist primarily of changes in fair value of financial instruments and losses on debt extinguishment, which are not currently allocated to our individual reportable segments.

**17. Supplemental Disclosure for Statements of Cash Flows**

During the nine-month periods ended September 30, 2017 and 2016, we paid interest aggregating $7.4 million $4.2 million, respectively. Interest paid during the nine-month period ended September 30, 2016 includes collection fees of $778,000 and a prepayment premium of $2.1 million, both of which were withdrawn by CRG from a bank account under their control. During the nine-month period ended September 30, 2017, we issued 1 million Series NN warrants to UCSD with an estimated fair value of $334,000. As discussed in Note 8, the liability for the additional $200,000 of investments made by Platinum was reclassified to additional paid-in-capital in January 2017. During the nine month-periods ended September 30, 2017 and 2016, we issued 105,308 and 67,002 shares of our common stock as matching contributions to our 401(k) Plan, which were valued at $53,707 and $120,800, respectively.

**18. Subsequent Events**

The Company has evaluated events and transactions subsequent to September 30, 2017 and through the date these consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the SEC.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**Forward-Looking Statements**

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

- general economic and business conditions, both nationally and in our markets;
- our history of losses and uncertainty of future profitability;
- the final outcome of the Term Loan Agreement with Capital Royalty Partners II L.P. and certain of its affiliates (collectively, "CRG") (the "CRG Loan Agreement") litigation in Texas;
- our ability to successfully complete research and further development of our drug candidates;
- the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates;
- our ability to successfully commercialize our drug candidates;
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- our ability to raise capital sufficient to fund our development and commercialization programs;
- our ability to implement our growth strategy;
- anticipated trends in our business;
- advances in technologies; and
- other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other SEC filings.

In addition, in this report, we use words such as "anticipate," "believe," "plan," "expect," "future," "intend," and similar expressions to identify forward-looking statements.

We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

**The Company**

Navidea Biopharmaceuticals, Inc. ("Navidea," the "Company," or "we"), a Delaware corporation (NYSE MKT: NAVB), is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on our Manocept™ platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making and targeted treatment.

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Lymphoseek® (technetium Tc99m tilmanocept) injection, the first product developed and commercialized by Navidea based on the platform.

On March 3, 2017, pursuant to an Asset Purchase Agreement, dated November 23, 2016 (the "Purchase Agreement"), the Company completed its previously announced sale to Cardinal Health 414, LLC ("Cardinal Health 414") of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the "Business"), including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration ("FDA") and similar indications approved by the FDA in the future (the "Product"), in Canada, Mexico and the United States (the "Territory") (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the "Asset Sale"). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement (the "Acquired Assets").

In connection with the closing of the Asset Sale, the Company entered into a License-Back Agreement (the "License-Back") with Cardinal Health 414. Pursuant to the License-Back, Cardinal Health 414 granted to the Company a sublicensable (subject to conditions) and royalty-free license to use certain intellectual property rights included in the Acquired Assets and owned by Cardinal Health 414 as of the closing of the Asset Sale to the extent necessary for the Company to (i) on an exclusive basis, subject to certain conditions, develop, manufacture, market, sell and distribute new pharmaceutical and other products that are not Competing Products (as defined in the License-Back), and (ii) on a non-exclusive basis, develop, manufacture, market, sell and distribute the Product throughout the world other than in the Territory. Subject to the Company's compliance with certain restrictions in the License-Back, the License-Back also restricts Cardinal Health 414 from using the intellectual property rights included in the Acquired Assets to develop, manufacture, market, sell, or distribute any product other than the Product or other product that (a) accumulates in lymphatic tissue or tumor-draining lymph nodes for the purpose of (1) lymphatic mapping or (2) identifying the existence, location or staging of cancer in a body, or (b) provides for or facilitates any test or procedure that is reasonably substitutable for any test or procedure provided for or facilitated by the Product. Pursuant to the License-Back and subject to rights under existing agreements, Cardinal Health 414 was given a right of first offer to market, sell and/or market any new products developed from the intellectual property rights licensed by Cardinal Health 414 to the Company by the License-Back.

As part of the Asset Sale, the Company and Cardinal Health 414 also entered into ancillary agreements providing for transitional services and other arrangements. The Company amended and restated its license agreement with The Regents of the University of California, San Diego ("UCSD") pursuant to which UCSD granted a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell the Product in the Territory.

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately $80.6 million after adjustments based on inventory being transferred and an advance of $3 million of guaranteed earnout payments as part of the CRG settlement (described below in Part II, Item 1 – Legal Proceedings), (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed $230 million over a period of ten years, of which $20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, $3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG (described below in Part II, Item 1 – Legal Proceedings).

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the "Supply and Distribution Agreement"), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination). At the closing of the Asset Sale, Cardinal Health 414 paid to the Company $1.2 million, as an estimate of the accrued revenue sharing payments owed to the Company as of the closing date, net of prior payments.

The Asset Sale to Cardinal Health 414 in March 2017 significantly improved our financial condition and our ability to continue as a going concern. The Company also continues working to establish new sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues.

The European Commission ("EC") granted marketing authorization for Tc99m tilmanocept in the EU in November 2014. We have completed manufacturing validation activities on a finished drug product contract manufacturing facility to support the Company's supply chain, primarily in Europe. This facility will produce a reduced-mass vial for which we received approval from the European Medicines Agency ("EMA") in September 2016. Following the January 2017 transfer of the Tc99m tilmanocept Marketing Authorization to our partner, SpePharm AG (an affiliate of Norgine BV), we transferred responsibility for manufacturing the reduced-mass vial for the EU market to SpePharm. During the second quarter of 2017, SpePharm launched Tc99m tilmanocept in select EU markets, providing a number of early adopters with sample doses to provide exposure to the product. EU sales commenced during the third quarter of 2017, however SpePharm has not yet reported or remitted any related revenue to the Company.

In June 2017, the Company entered into an exclusive license and distribution agreement with Sayre Therapeutics for the development and commercialization of Tc99m tilmanocept in India. Sayre Therapeutics specializes in innovative treatments and medical device commercialization in South Asia. Under the terms of the agreement, Navidea received an upfront payment of $100,000 and is eligible to receive additional milestone payments and double-digit royalties associated with the sale of Tc99m tilmanocept in India.

Other than Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, none of the Company's drug product candidates have been approved for sale in any market.

**Product Line Overview**

Our primary development efforts over the last few years have been focused on diagnostic products, including Lymphoseek which was sold to Cardinal Health 414 in March 2017, as well as other diagnostic and therapeutic line extensions based on our Manocept platform.

The flexible and versatile Manocept platform acts as an engine for the design of targeted imaging molecules applicable to a range of diagnostic modalities, including single photon emission computed tomography ("SPECT"), positron emission tomography ("PET"), gamma-scanning (both imaging and topical) and intra-operative and/or optical-fluorescence detection; active clinical diagnostic programs in four diseases representing both major macrophage activation states are ongoing.

Cardiovascular Disease ("CV") – A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed subcutaneously was completed (ClinicalTrials.gov NCT02542371). The results of this study were recently published in early release in the *Journal of Infectious Diseases* in January 2017 (published in the circulated version, *J Infect Dis* (2017) **215** (8): 1264-1269), confirming that the Tc99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch (NIH/NHLBI Grant 1 R43 HL127846-01). We have applied for follow-on NIH/NHLBI support to fund additional clinical studies. These studies are currently under development and design for both Phase 1 and Phase 2 trials.

Rheumatoid Arthritis ("RA") – Two Tc99m tilmanocept dose escalation studies in RA have been initiated. The first study, now complete (ClinicalTrials.gov NCT02683421), included 18 subjects (9 with active disease and 9 healthy subjects) dosed subcutaneously with 50 and 200 µg/2mCi Tc99m tilmanocept. In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have initiated and nearly completed a study involving intravenous ("IV") dosing of Tc99m tilmanocept (ClinicalTrials.gov NCT02865434). These studies have been supported through a Small Business Innovation Research ("SBIR") grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1).

Kaposi's Sarcoma ("KS") – Although we initiated and completed a study of KS in 2015 (ClinicalTrials.gov NCT022201420), we received additional funding from the National Institutes of Health ("NIH") in 2016 to continue studies in this disease. The new support not only continues the imaging of the cutaneous form of this disease but expands this to imaging of visceral disease via IV administration of Tc99m tilmanocept (NIH/NCI 1 R44 CA192859-01A1; ClinicalTrials.gov NCT03157167). Additionally, we received funding to support the therapeutic initiative for KS employing a select form of the MT-1002 agent under current evaluation. The Company has already completed a portion of the Phase 1 SBIR portion of this award (1 R44 CA206788-01).

Colorectal Cancer ("CRC") and Synchronous Liver Metastases – During the first quarter of 2017, we initiated an imaging study in subjects with CRC and liver metastases via IV administration of Tc99m tilmanocept. This study is ongoing and will enroll up to 12 subjects with dose modification. This study is supported through a SBIR grant (1 R44 CA1962783-01A1; ClinicalTrials.gov NCT03029988).

Based on performance in these very large imaging market opportunities the Company anticipates continued investment in these programs including initiating studies designed to obtain new approvals for the Tc99m tilmanocept product.

The Company has completed preclinical studies employing both MT 1000-class and 2000-class therapeutic conjugates of Manocept. The highly positive results from these studies are indicative of Manocept's specific targeting supported by its notable binding affinity to CD206 receptors. This high specificity is a foundation of the potential for this technology to be useful in treating diseases linked to the over-activation of macrophages. This includes various cancers as well as autoimmune, infectious, CV, and central nervous system ("CNS") diseases. Our efforts in this area were further supported by the 2015 formation of MT, a majority-owned subsidiary that was formed specifically to explore therapeutic applications for the Manocept platform.

MT has been set up to pursue the therapeutic drug delivery model. This model enables the Company to leverage its technology over many potential disease applications and with multiple partners simultaneously without significant capital outlays. To date, the Company has developed two lead families of therapeutic products. The MT-1000 class is designed to deplete activated macrophages via apoptosis. The MT-2000 class is designed to modulate activated macrophages from a classically activated phenotype to the alternatively activated phenotype. Both families have been tested in a number of disease models in rodents.

We continue to seek to partner or out-license NAV4694. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau Technologies, Inc. ("Cerveau"), outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims. See Part II – Item 1 – Legal Proceedings.

The NAV5001 sublicense was terminated in April 2015.

*Manocept Platform - Diagnostics and Therapeutics Background*

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform serves as an engine for purpose-built molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This disease-targeted drug platform provides the capability to utilize a breadth of diagnostic modalities, including SPECT, PET, gamma-scan (both imaging and topical), intra-operative and/or optical-fluorescence detection, as well as delivery of therapeutic compounds that target macrophages, and their role in a variety of immune- and inflammation-based disorders. The FDA-approved sentinel node/lymphatic mapping agent, Tc99m tilmanocept, is representative of the ability to successfully exploit this mechanism to develop powerful new products.

Impairment of the macrophage-driven disease mechanisms is an area of increasing and proven focus in medicine. The number of people affected by all the inflammatory diseases combined is estimated at more than 40 million in the United States and perhaps 700 million worldwide, making macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including RA, atherosclerosis/vulnerable plaque, nonalcoholic steatohepatitis ("NASH"), inflammatory bowel disease, systemic lupus erythematosus, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, CNS diseases, and inflammation.

*Manocept Platform – Immuno-Diagnostics Clinical Data*

*Rheumatoid Arthritis*

In conjunction with the agreed submission of an investigational new drug ("IND") amendment for IV administration of tilmanocept to the FDA, we initiated a multi-center Phase 1/2 registrational trial employing IV administration to evaluate tilmanocept for the primary diagnosis of RA and to aid in the differential diagnosis of RA from other types of inflammatory arthritis. The first subject was dosed and imaged in February 2017. This study will enroll up to 33 subjects with dose escalation (ClinicalTrials.gov NCT02865434; Study supported by NIH/NIAMSD Grant 1 R44 AR067583-01A1).

*Cardiovascular Disease*

Results of our studies to date (ClinicalTrials.gov NCT02542371) provide strong evidence of the potential of Tc99m tilmanocept to accumulate in high risk morphology plaques, the ability to make preliminary comparisons of aortic Tc99m tilmanocept uptake by SPECT/CT in clinically symptomatic patients vs. healthy age-matched subjects, and to evaluate the ability of Tc99m tilmanocept to identify the same aortic atherosclerotic plaques that are identified by contrast enhanced coronary computed tomography angiography and/or PET/CT.

*Nonalcoholic Steatohepatitis*

The Company has initiated a clinical study examining the safety and efficacy of Tc99m radiolabel escalation of IV-injected Tc99m tilmanocept in SPECT/CT imaging studies to identify and quantify the extent of nonalcoholic steatohepatitis ("NASH") lesions in human patients. We have received Institutional Review Board ("IRB") approval of the clinical protocol, and we plan to initiate this Phase 1 clinical study in NASH in late 2017.

*Other Immuno-Diagnostic Applications*

The Company has received an award for a Fast Track SBIR grant providing for up to $1.8 million from the NIH's National Cancer Institute to fund preclinical studies examining the safety of IV injection of Tc99m tilmanocept, a Manocept platform product, followed by a clinical study providing the initial evaluation of the safety and efficacy of SPECT/CT imaging studies with IV Tc99m tilmanocept to identify and quantify both skin- and organ-associated KS lesions in human patients. The grant is awarded in two parts with the potential for total grant money of up to $1.8 million over two and a half years. The first six-month funding segment of $300,000, which has already been awarded, enabled Navidea to secure necessary collaborations and Institutional Review Board approvals. We have now been awarded the remaining portion of the second funding segment, which provided an additional $1.5 million to accrue participants, perform the Phase 1/2 study and perform data analyses to confirm the safety and effectiveness of intravenously administered Tc99m tilmanocept. We have received IRB approval of the clinical protocol, and we plan to initiate a Phase 1/2 clinical study in KS in late 2017.

*Macrophage Therapeutics Background*

MT has developed processes for producing the first two therapeutic Manocept immuno-constructs, MT-1002, designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. MT has contracted with independent facilities to produce sufficient quantities of the MT-1002 and MT-2002 agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

*Manocept Platform – In-Vitro and Pre-Clinical Immunotherapeutics Data*

The novel MT-1002 construct is designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their tumor-associated macrophages potentially altering the course of cancer. KS is a serious and potentially life threatening illness in persons infected with HIV and the third leading cause of death in this population worldwide. The prognosis for patients with KS is poor with high probabilities for mortality and greatly diminished quality of life. The funds for this Fast Track grant will be released in three parts, which together have the potential to provide up to $1.8 million in resources over 2.5 years with the goal of completing an IND submission for a Manocept construct (MT-1000 class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. The first part of the grant provided $232,000 to support analyses including in vitro and cell culture studies now complete and will be followed by Part 2 and 3 FDA-required preclinical animal testing studies. The information from these studies will be combined with other information in an IND application that will be submitted to the FDA requesting permission to begin testing the compound in selected KS subjects.

Navidea and MT continue to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS, RA and infectious diseases. The immuno-inflammatory process is remarkably complex and tightly regulated with indicators that initiate, maintain and shut down the process. Macrophages are immune cells that play a critical role in the initiation, maintenance, and resolution of inflammation. They are activated and deactivated in the inflammatory process. Because macrophages may promote dysregulation that accelerates or enhances disease progression, diagnostic and therapeutic interventions that target macrophages may open new avenues for controlling inflammatory diseases. There can be no assurance that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

Navidea and MT have already reported on the peripheral infectious disease aspects of KS, including HIV and HHV8 (CROI, Boston 2016, and KS HHV8 Summit Miami 2015). As noted Navidea and MT continue this work funded by the NIH/NIAID and NCI.

Nonalcoholic fatty liver disease (“NAFLD”) is a spectrum of liver disorders and is defined by the presence of steatosis in more than 5% of hepatocytes with little or no alcohol consumption. NASH is the most extreme form of NAFLD. A major characteristic of NASH involves cells undergoing lipotoxicity, releasing endogenous signals prompting the accumulation of various macrophages to assess the damage. Studies have shown that levels of endogenous molecular inflammatory signals positively correlate with inflammation, hepatocyte ballooning, and other NAFLD symptoms. Navidea and MT have developed a molecular delivery technology capable of targeting only the disease-causing macrophages by selectively binding to the CD206 receptor. Selective binding and efficient delivery of this agent mitigates the potential of affecting the neighboring cells or interfering more broadly with the normal function of the immune system.

We have completed four in vivo studies employing our MT-1002 and MT-2002 Manocept conjugates in a well-established mouse model of NAFLD/NASH and liver fibrosis. The NALFD scores, which correlate to the agents’ effectiveness, were significantly reduced, with all the activity related to inflammation and “ballooning” scores. Fibrosis decreased significantly when compared to the control in the later dosing arm of the study. Liver weights did not differ during any phase of the study between control and agent-treated groups, nor was there any evidence of damage to the roughly 30% of the liver made up of un-activated macrophages called Kupffer cells. MT-1002 and MT-2002 both significantly reduced key disease assessment parameters in the in vivo STAM$^{TM}$ NASH model. We believe these agents present themselves as potential clinically effective candidates for further evaluation. We continue to use this model to further assess the activity of our agents.

Navidea and MT have already reported on the peripheral infectious disease aspects of KS, including HIV and HHV8 (CROI, Boston 2016, and KS HHV8 Summit Miami 2015). As noted Navidea and MT continue this work funded by the NIH/NIAID and NCI.

We have now completed an expanded series of predictive in vitro screening tests of the MT-1002 and MT-2002 therapeutic conjugates against the Zika and Dengue viruses, which included infectivity and viral replication inhibition effectiveness as well as dose finding studies and mechanisms of action, the latter based on conjugate structures. We have also completed a series of predictive in vivo screening tests of the MT-1002 and MT-2002 therapeutic conjugates against Leishmaniosis, which included host cell targeting and killing effectiveness as well as dose finding studies and mechanisms of action. A portion of the results from the *in vivo* Leishmaniosis study, completed in conjunction with the National Institute of Allergy and Infectious Diseases/NIH, was recently accepted for publication in the *Journal of Experimental Medicine.* The results from all evaluations were positive and have provided a basis for moving forward with additional *in vivo* testing of the selected conjugates. We have selected collaborators for these *in vivo* studies, which we expect will take place over the next four to six months. We will provide updates as information becomes available on future testing.

*NAV4694 (Candidate for Divestiture)*

NAV4694 is a fluorine-18 (“F-18”) labeled PET imaging agent being developed as an aid in the imaging and evaluation of patients with signs or symptoms of Alzheimer’s disease (“AD”) and mild cognitive impairment (“MCI”). NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in PET scans. Amyloid plaque pathology is a required feature of AD and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD. Patients who are negative for amyloid pathology do not have AD. NAV4694 has been studied in rigorous pre-clinical studies and clinical trials in humans. Clinical studies through Phase 3 have included subjects with MCI, suspected AD patients, and healthy volunteers. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity.

In May 2014, the Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Tc99m tilmanocept revenue. This realignment primarily involved reducing our near-term support for our neurological product candidates, including NAV4694, as we sought a development partner or partners for these programs. The Company is currently engaged in discussions related to the potential partnering or divestiture of NAV4694. We continue to have active interest from potential partners or acquirers; however, our negotiations have experienced delays due in large part to litigation brought by Sinotau, one of the potential partners. In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and on July 20, 2017, the parties filed a joint motion to stay the case for 60 days pending settlement discussion. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau Technologies, Inc. ("Cerveau"), outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims.

*NAV5001 (In-License Terminated)*

NAV5001 is an iodine-123 (I-123) labeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson's disease ("PD") and other movement disorders, with potential use as a diagnostic aid in dementia. The agent binds to the dopamine transporter ("DAT") on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a hallmark of PD. In addition to its potential use as an aid in the differential diagnosis of PD and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies, one of the most common forms of dementia after AD.

In May 2014, the Board of Directors decided to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Lymphoseek revenue. This realignment primarily involved reducing our near-term support for our neurological product candidates, including NAV5001.

In April 2015, the Company entered into an agreement with Alseres Pharmaceuticals, Inc. ("Alseres") to terminate the sub-license agreement, dated July 31, 2012, for research, development and commercialization of NAV5001. Under the terms of this agreement, Navidea transferred all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres agreed to reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, Navidea has supplied clinical support services for NAV5001 on a cost-plus reimbursement basis. However, to this point, Alseres has been unsuccessful in raising the funds necessary to restart the program and reimburse Navidea. As a result, we have taken steps to end our obligations under the agreement and notified Alseres that we consider them in breach of the agreement. We are in the process of trying to recover the funds we expended complying with our obligations under the termination agreement.

**Outlook**

Our operating expenses in recent years have been focused primarily on support of Tc99m tilmanocept, our Manocept platform, and NAV4694 and NAV5001 product development. We incurred approximately $2.8 million and $5.0 million in total on research and development activities during the nine-month periods ended September 30, 2017 and 2016, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred out-of-pocket charges by program as follows:

| | Nine Months Ended September 30, | |
|---|---|---|
| **Development Program** [(a)] | **2017** | **2016** |
| Tc99m Tilmanocept (Lymphoseek) | $ 187,829 | $ 1,060,459 |
| Manocept Platform | 1,209,024 | 663,536 |
| Macrophage Therapeutics | 436,277 | 561,601 |
| NAV4694 [(b)] | (399,146) | 1,332,369 |
| NAV5001 [(b)] | (28,176) | 101,997 |

(a) Amounts reflect projects included in discontinued operations in the consolidated statements of operations. Certain development program expenditures were offset by grant reimbursement revenues totaling $1.3 million and $2.0 million during the nine-month periods ended September 30, 2017 and 2016, respectively.

(b) Changes in cost estimates resulted in the reversal of certain previously accrued expenses related to the NAV4694 and NAV5001 development programs during the nine-month period ended September 30, 2017.

We expect to continue the advancement of our efforts with our Manocept platform during the remainder of 2017 and into 2018. The divestiture of NAV5001 and the suspension of active patient accrual in our NAV4694 trials have decreased our development costs over the past year, however, we continue to incur costs to maintain the NAV4694 trials while we complete our partnering/divestiture activities. We expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be lower in 2017 than in 2016.

Tc99m tilmanocept is approved by the EMA for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity in the EU. Following the January 2017 transfer of the Tc99m tilmanocept Marketing Authorization to SpePharm, we transferred responsibility for manufacturing the reduced-mass vial for the EU market to SpePharm. During the second quarter of 2017, SpePharm launched Tc99m tilmanocept in select EU markets, providing a number of early adopters with sample doses to provide exposure to the product. EU sales commenced during the third quarter of 2017, however SpePharm has not yet reported or remitted any related revenue to the Company. We anticipate that we will incur costs related to supporting our product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market.

We continue to evaluate existing and emerging data on the potential use of Manocept-related agents in the diagnosis and disease-staging of disorders in which macrophages are involved, such as KS, RA, vulnerable plaque/atherosclerosis, TB and other disease states, to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. We are also evaluating potential funding and other resources required for continued development, regulatory approval and commercialization of any Manocept platform product candidates that we identify for further development, and potential options for advancing development. There can be no assurance that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

**Discontinued Operations**

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under "The Company." In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately $80.6 million after adjustments based on inventory being transferred and an advance of $3.0 million of guaranteed earnout payments as part of the CRG settlement, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed $230 million over a period of ten years, of which $20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, $3.0 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG.

We recorded a net gain on the sale of the Business of $86.9 million for the nine months ended September 30, 2017, including $16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by $3.3 million in estimated fair value of warrants issued to Cardinal Health 414, $2.0 million in legal and other fees related to the sale, $800,000 in net balance sheet dispositions and write-offs, and $6.4 million in estimated taxes.

Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Business as a discontinued operation. Cash flows associated with the operation of the Business have been combined with operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

**Results of Operations**

This discussion of our Results of Operations focuses on describing results of our operations as if we had not operated the discontinued operations discussed above during the periods being disclosed. In addition, since our remaining pharmaceutical product candidates are not yet generating commercial revenue, the discussion of our revenue focuses on the grant and other revenue and our operating variances focus on our remaining product development programs and the supporting general and administrative expenses.

*Three Months Ended September 30, 2017 and 2016*

*Tc99m Tilmanocept License Revenue.* During the third quarter of 2016, we recognized $667,000 of the $2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of $417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During the third quarter of 2016, we also recognized $500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as $127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Lymphoseek distribution agreement for Europe. No license revenue was recognized during the third quarter of 2017.

*Grant and Other Revenue.* During the third quarter of 2017, we recognized $224,000 of grant and other revenue, compared to $511,000 in the third quarter of 2016. Grant revenue during the third quarter of 2017 was primarily related to SBIR grants from the NIH supporting Manocept development. Grant revenue during the third quarter of 2016 was primarily related to SBIR grants from the NIH supporting Manocept, Tc99m tilmanocept and NAV4694 development.

*Research and Development Expenses.* Research and development expenses decreased $45,000, or 5%, to $875,000 during the third quarter of 2017 from $919,000 during the same period in 2016. The decrease was primarily due to decreased net compensation costs of $86,000 including salaries and incentive-based awards due to net decreased headcount and net decreases in other support costs such as travel of $25,000; offset by net increases in drug project expenses related to (i) increased Manocept development costs of $279,000 including increased clinical trial costs and pre-clinical testing; offset by (ii) decreased therapeutics development costs of $125,000 including decreased consulting costs, manufacturing-related activities and pre-clinical testing; (iii) decreased NAV4694 development costs of $61,000 including decreased manufacturing-related activities and clinical trial costs while we continued our efforts to divest the program; and (iv) decreased NAV5001 development costs of $35,000 related to decreased manufacturing-related activities.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses decreased $77,000, or 4%, to $1.7 million during the third quarter of 2017 from $1.8 million during the same period in 2016. The net decrease was primarily due to net decreases in general support costs of $139,000 including rent and other office-related costs and depreciation, and decreased net compensation costs of $13,000 including decreased salaries and fringe benefits; offset by net increased legal and professional services of $74,000.

*Other Income (Expense).* Other income, net, was $69,000 during the third quarter of 2017 compared to other expenses, net of $852,000 during the same period in 2016. During the third quarter of 2017, we recognized interest income of $102,000 primarily related to the guaranteed consideration due from Cardinal Health 414, which was discounted to present value at the closing date of the Asset Sale. Also during the third quarter of 2017, $29,000 of interest expense was compounded and added to the balance of our note payable to Platinum. During the third quarter of 2016, we recorded non-cash losses of $839,000 related to changes in the estimated fair value of financial instruments.

*Nine Months Ended September 30, 2017 and 2016*

*Tc99m Tilmanocept License Revenue.* During the first nine months of 2017, we recognized license revenue of $100,000 for a non-refundable upfront payment related to the Tc99m tilmanocept license and distribution agreement with Sayre Therapeutics in India. During the same period in 2016, we recognized $1.2 million of the $2.0 million non-refundable upfront payment received by the Company related to the Tc99m tilmanocept license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of $417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During the first nine months of 2016, we also recognized $500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as $127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Tc99m tilmanocept distribution agreement for Europe.

*Grant and Other Revenue.* During the first nine months of 2017, we recognized $1.3 million of grant and other revenue compared to $2.1 million in the same period in 2016. Grant revenue during the first nine months of 2017 was primarily related to SBIR grants from the NIH supporting Manocept and Tc99m tilmanocept development. Grant revenue during the first nine months of 2016 was primarily related to SBIR grants from the NIH supporting NAV4694, Manocept and Tc99m tilmanocept development. Other revenue for the first nine months of 2017 and 2016 included $31,000 and $85,000, respectively, of revenue from our marketing partners in Europe and China related to development work performed at their request.

*Research and Development Expenses.* Research and development expenses decreased $2.2 million, or 45%, to $2.8 million during the first nine months of 2017 from $5.0 million during the same period in 2016. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of $1.7 million including decreased manufacturing-related activities, clinical trial costs and licensing costs while we continued our efforts to divest the program; (ii) decreased Tc99m tilmanocept development costs of $533,000 including decreased manufacturing-related activities and regulatory costs; (iii) decreased NAV5001 development costs of $130,000 related to decreased manufacturing-related activities and clinical trial costs; and (iv) decreased therapeutics development costs of $125,000 including decreased consulting costs offset by increased internal time; offset by (v) increased Manocept development costs of $674,000 including increased clinical trial costs and pre-clinical testing, offset by decreased licensing costs. The decrease was also due to decreased net compensation costs of $331,000 including salaries and incentive-based awards due to net decreased headcount and net decreases in other support costs of $67,000 including general office expenses and travel.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased $3.2 million, or 54%, to $9.0 million during the first nine months of 2017 from $5.8 million during the same period in 2016. The net increase was primarily due to increased legal and professional services of $1.2 million, a loss on disposal of assets related to our previous office space of $720,000, termination costs related to the arbitration award to Mr. Gonzalez of $481,000, loss on termination of our previous office lease of $429,000, and increased general and administrative net compensation costs of $416,000 including increased incentive-based awards offset by decreased salaries and fringe benefits.

*Other Income (Expense).* Other expense, net, was $1.1 million during the first nine months of 2017 as compared to other income, net of $1.6 million during the same period in 2016. We recorded a loss on extinguishment of the CRG debt of $1.3 million during the first nine months of 2017. Also during the first nine months of 2017, we recognized interest income of $236,000 primarily related to the guaranteed consideration due from Cardinal Health 414, which was discounted to present value at the closing date of the Asset Sale. During the first nine months of 2017, $68,000 of interest expense was compounded and added to the balance of our note payable to Platinum. For the first nine months of 2017 and 2016, we recorded non-cash income of $153,000 and $1.8 million, respectively, related to changes in the estimated fair value of financial instruments. During the first nine months of 2016, we recorded a non-cash loss on the disposal of our investment in R-NAV, LLC ("R-NAV") of $40,000.

**Liquidity and Capital Resources**

Cash balances increased to $4.6 million at September 30, 2017 from $1.5 million at December 31, 2016. The net increase was primarily due to net cash received for the Asset Sale to Cardinal Health 414, offset by payments made on the CRG and Platinum debts and investments in available-for-sale securities coupled with cash used to fund our operations.

All of our material assets were pledged as collateral for our borrowings under the CRG Loan Agreement. In addition to the security interest in our assets, the CRG Loan Agreement carried covenants that imposed significant requirements on us. An event of default entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

As previously described, on March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid $59 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Texas hearing is currently set for early December 2017.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately $1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

As of September 30, 2017, the outstanding principal balance of the Platinum Note was approximately $2.0 million.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been alleviated. Based on our current working capital and our projected cash burn, including the potential for the Company to pay up to an additional $7 million to CRG depending upon the outcome of the Texas litigation, management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q. Our projected cash burn also factors in certain cost cutting initiatives that have been implemented and approved by the board of directors, including reductions in the workforce and a reduction in facilities expenses. Additionally, we have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. We believe all of these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern.

*Operating Activities.* Cash provided by operations was $59.7 million during the first nine months of 2017 compared to $1.3 million provided during the same period in 2016.

In connection with the Asset Sale, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately $80.6 million after adjustments based on inventory being transferred and an advance of $3 million of guaranteed earnout payments as part of the CRG settlement, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to offset. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed $230 million over a period of ten years, of which $20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, $3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG.

We recorded a net gain on the sale of the Business of $ 86.9 million for the nine months ended September 30, 2017, including $16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by $3.3 million in estimated fair value of warrants issued to Cardinal Health 414, $2.0 million in legal and other fees related to the sale, $800,000 in net balance sheet dispositions and write-offs, and $6.4 million in estimated taxes.

Accounts and other receivables increased to $8.0 million at September 30, 2017 from $203,000 at December 31, 2016, primarily related to the current portion of the guaranteed earnout due from Cardinal Health 414, which was discounted and recorded at present value. The change in accounts and other receivables also reflects a decrease in receivables from our European distribution partner.

Inventory levels decreased to $0 at September 30, 2017 from $96,000 at December 31, 2016, primarily due to the use of materials for European manufacturing development and production. We expect inventory levels to remain minimal during the remainder of 2017 as European manufacturing has been transitioned to our distribution partner.

Prepaid expenses and other current assets decreased to $505,000 at June 30, 2017 from $842,000 at December 31, 2016, primarily due to decreased legal retainers and amortization of prepaid insurance, offset by increased prepaid investor relations and other services and increased interest receivable related to the guaranteed earnout due from Cardinal Health 414.

Accounts payable decreased to $1.2 million at September 30, 2017 from $5.2 million at December 31, 2016, primarily driven by net decreased payables due to legal and professional services, NAV4694, regulatory and operations vendors. Accrued liabilities and other current liabilities decreased to $2.5 million at September 30, 2017 from $7.9 million at December 31, 2016, primarily driven by decreased accruals for interest, NAV4694, bonuses and Macrophage Therapeutics costs, offset by increased accruals for taxes and Manocept development costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we continue to decrease our level of development activity related to NAV4694, offset by planned increases in development activity related to the Manocept platform.

Assets associated with discontinued operations decreased to $0 at September 30, 2017 from $3.1 million at December 31, 2016, and liabilities associated with discontinued operations decreased to $33,000 at September 30, 2017 from $4.9 million at December 31, 2016. Decreases in both assets and liabilities associated with discontinued operations were primarily due to the Asset Sale to Cardinal Health 414 in March 2017.

*Investing Activities.* Investing activities used $2.0 million during the first nine months of 2017 compared to $39,000 during the same period in 2016. Investing activities during the first nine months of 2017 included purchases of available-for-sale securities of $2.2 million and capital expenditures of $31,000, primarily for computer equipment and leasehold improvements, offset by maturities of available-for-sale securities of $200,000. Investing activities during the first nine months of 2016 included net payments related to the disposal of our investment in R-NAV of $82,000 and capital expenditures of $2,000, primarily for computer equipment, offset by proceeds from sales of capital equipment of $45,000. We expect our overall capital expenditures for the remainder of 2017 will be higher than for the same period in 2016 related to our office move.

*Financing Activities.* Financing activities used $54.6 million during the first nine months of 2017 compared to $7.6 million during the same period in 2016. The $54.6 million used by financing activities in the first nine months of 2017 consisted primarily of principal payments on the CRG, Platinum and IPFS notes payable of $59.7 million, offset by the release of restricted cash of $5.0 million and proceeds from issuance of common stock of $54,000. The $7.6 million used by financing activities in the first nine months of 2016 consisted primarily of payment of debt-related costs of $3.9 million, restrictions placed on cash in an account controlled by CRG of $3.5 million, and principal payments on notes payable of $189,000, all related to the CRG debt.

*Capital Royalty Group Debt*

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the $59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than $47 million and no more than $66 million. In addition, CRG agreed that Navidea had the right to assert all affirmative defenses to its claim of default. In the underlying case the district court had entered summary judgment in favor of CRG finding unspecified events of default but refusing to consider affirmative defenses raised by Navidea as not before the Court. Subsequent to the settlement CRG moved again for entry of judgment in its favor; Navidea objected that the Settlement Agreement specifically allowed it to raise affirmative defenses and the district court agreed with Navidea setting the case for trial in December 2017. CRG has once again indicated it intends to move for summary judgment, a motion Navidea intends to vigorously dispute.

Concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a $7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a $12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of $59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The $2 million being held in escrow pursuant to court order in the Ohio case and the $3 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. The Texas hearing is currently set for early December 2017.

*Platinum Credit Facility*

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which was purportedly transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum Note. Such balance of approximately $1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

As of September 30, 2017, the outstanding principal balance of the Platinum Note was approximately $2.0 million.

*Summary*

Our future liquidity and capital requirements will depend on a number of factors, including the final outcome of the CRG litigation which could potentially result in payment of up to an additional $7 million to CRG, the ability of our distribution partners to achieve market acceptance of our products, our ability to complete the development and commercialization of new products, our ability to monetize our investment in non-core technologies, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by the FDA and international regulatory bodies, the ability to procure required financial resources, and intellectual property protection.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been removed. The Company is also working to establish additional sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to sustainable levels. Substantial progress on the Manocept platform has resulted in several promising opportunities.

We plan to focus our resources for the remainder of 2017 primarily on defending our position related to CRG's claims of default and development of products based on the Manocept platform. Although management believes that it will be able to achieve these objectives, they are subject to a number of variables beyond our control, including the outcome of the remaining CRG litigation, the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently there can be no assurance that we will be able to achieve our objective of bringing our expenses in line with our revenues, and we may need to seek additional debt or equity financing if we cannot achieve that objective in a timely manner.

During 2016 and 2017 to date, we continued making limited investment in the NAV4694 clinical trial process based on our expectation that we will ultimately be successful in securing a partnership that will provide us some level of return on this investment which is incremental to the carrying costs we are presently incurring. However, there can be no assurance that the partnership discussions in which we are engaged will yield the level of return we are anticipating.

Based on our current working capital and our projected cash burn, including the potential for the Company to pay up to an additional $7 million to CRG depending upon the outcome of the Texas litigation, management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q. Our projected cash burn also factors in certain cost cutting initiatives that have been implemented and approved by the board of directors, including reductions in the workforce and a reduction in facilities expenses. Additionally, we have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. We believe all of these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern

We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. There can be no assurance that if we attempt to raise additional capital through debt, royalty, equity or otherwise, we will be successful in doing so on terms acceptable to the Company, or at all. Further, there can be no assurance that we will be able to gain access and/or be able to execute on securing new sources of funding, new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

**Off-Balance Sheet Arrangements**

As of September 30, 2017, we had no off-balance sheet arrangements.

**Recent Accounting Standards**

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will supersede existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is that a company should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process that requires companies to exercise more judgment and make more estimates than under the current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. Since the issuance of ASU 2014-09, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. ASU 2014-09 allows a choice of transition methods: (a) a full retrospective adoption in which the standard is applied to all of the periods presented, or (b) a modified retrospective adoption in which the standard is applied only to the most current period presented in the financial statements with a cumulative-effect adjustment reflected in retained earnings. ASU 2014-09 also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity's nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those periods.

Following the sale of the Business to Cardinal Health 414 in March 2017, we generate revenue primarily from grants to support certain of our product development programs. Such grant revenues are recognized only after expenses reimbursable under the grants have been paid. We also earn revenues related to our licensing and distribution agreements. The consideration we are eligible to receive under our licensing and distribution agreements typically includes upfront payments, reimbursement for research and development costs, milestone payments, and royalties. Each licensing and distribution agreement is unique and will require separate assessment using the five-step process under ASU 2014-09. Management is working to complete its evaluation of the impact of adopting ASU 2014-09, however we currently do not anticipate that it will have a material effect on our consolidated financial statements. We will adopt ASU 2014-09 along with additional related ASUs effective January 1, 2018. We currently plan to use the modified retrospective method of adoption.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*. ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a "set") is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. Management is currently evaluating the impact that the adoption of ASU 2017-01 will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all of the following criteria are met: (1) The fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. Disclosure requirements remain unchanged. ASU 2017-09 is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted as described in ASU 2017-09. Management is currently evaluating the impact that the adoption of ASU 2017-09 will have on our consolidated financial statements.

In September 2017, the FASB issued ASU No. 2017-13, *Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842)*. ASU 2017-13 adds SEC paragraphs pursuant to an SEC Staff Announcement made in July 2017 and clarifies several issues related to transition and implementation of the covered topics, including clarification of the definition of a public business entity, the effect of a change in tax law or rates on leveraged leases, and related amendments to the eXtensible Business Reporting Language ("XBRL") taxonomy. Management is currently evaluating the impact that the adoption of ASU 2017-13 will have on our consolidated financial statements.

**Critical Accounting Policies**

*We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Quarterly Report on Form 10-Q, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained in our Annual Report on Form 10-K. We include within these policies our "critical accounting policies." Critical accounting policies are those policies that are most important to the preparation of our consolidated financial statements and require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition.*

*Revenue Recognition.* We currently generate revenue primarily from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due.

We earn additional revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

*Research and Development.* Research and development ("R&D") expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits, and stock-based compensation, as well as travel, supplies, and other costs to support our R&D staff. External contracted services include clinical trial activities, chemistry, manufacturing and control-related activities, and regulatory costs. R&D expenses are charged to operations as incurred. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base these estimates and assumptions upon historical experience and existing, known circumstances. Actual results could differ from those estimates. Specifically, management may make significant estimates in the following areas:

- *Stock-Based Compensation.* Stock-based payments to employees and directors, including grants of stock options and restricted stock, are recognized in the statements of operations based on their estimated fair values on the date of grant, subject to an estimated forfeiture rate. The fair value of each option award with time-based vesting provisions is estimated on the date of grant using the Black-Scholes option pricing model to value such stock-based payments and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using the Black-Scholes option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors. The fair value of each option award with market-based vesting provisions is estimated on the date of grant using a Monte Carlo simulation to value such stock-based payments and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using a Monte Carlo simulation is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors.

  We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior. Restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award.

  Since stock-based compensation is recognized only for those awards that are ultimately expected to vest, we have applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

- *Fair Value of Financial Instruments.* Certain of our notes payable are required to be recorded at fair value. The estimated fair value of our debt is calculated using a Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. For the debt recorded at fair value, unrealized gains and losses on the fair value of the debt are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations.

- *Fair Value of Warrants.* We estimate the fair value of warrants using the Black-Scholes model, which is affected by our stock price and warrant exercise price, as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility and risk-free interest rate.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

*Interest Rate Risk.* As of September 30, 2017, our $4.6 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these accounts, we believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of September 30, 2017, the interest rate on certain of our debt obligations was the greater of: (a) the U.S. prime rate as reported in The Wall Street Journal plus 6.75%, and (b) 10.0%; both of the above rates reduced by 600 basis points (effective interest rate as of September 30, 2017 was 8.125%). Based on the amount of our variable-rate borrowings at September 30, 2017, which totaled approximately $2.0 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately $20,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreement, a decrease in the U.S. prime rate would not affect our annual interest expense.

*Foreign Currency Exchange Rate Risk.* We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the nine-month periods ended September 30, 2017 and 2016, we recorded foreign currency transaction (losses) gains of approximately $(39,000) and $43,000, respectively.

*Equity Price Risk.* We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. The fair value of certain of our warrant liabilities is determined using various inputs and assumptions, several of which are based on a survey of peer group companies since the warrants are exercisable for common stock of a non-public subsidiary company. As of September 30, 2017, we had approximately $63,000 of derivative liabilities recorded on our balance sheet related to outstanding MT warrants. Due to the relatively low valuation of the MT warrants, a hypothetical 50% change in our stock price would not have a material effect on the consolidated financial statements.

**Item 4. Controls and Procedures**

**Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized, and reported within the specified time periods. As a part of these controls, our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of September 30, 2017. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Based on our evaluation, our management has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed and are effective.

Our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2016, we identified the following material weaknesses:

- The Company did not maintain adequate controls to ensure that information pertinent to the Company’s operations were analyzed and communicated by and between financial and non-financial management personnel of the Company. Management has concluded that this control deficiency represented a material weakness.

- The Company did not maintain effective oversight of the Company’s external financial reporting and internal control over financial reporting by the Company’s Audit Committee. Management has concluded that this control deficiency represented a material weakness.

**Changes in Control Over Financial Reporting**

Following identification of these material weaknesses, we have worked diligently to improve communication between management and the Board of Directors, including committees. We have taken steps to (i) ensure adequate communication between management, the Board of Directors, and its committees, and (ii) educate the Board of Directors, including its committees, about their role in maintaining effective oversight of the Company’s financial reporting processes. As a result, our management considers the material weaknesses to be corrected.

Except for the change noted above, during the quarter ended September 30, 2017, there were no other changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

*Sinotau Litigation – NAV4694*

On August 31, 2015, Hainan Sinotau Pharmaceutical Co., Ltd. (“Sinotau”) filed a suit for damages, specific performance, and injunctive relief against the Company in the U.S. District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company’s NAV4694 product candidate and technology (the “Sinotau Litigation”). In September 2016, the Court denied the Company’s motion to dismiss. The Company filed its answer to the complaint and on July 20, 2017, the parties filed a joint motion to stay the case for 60 days pending settlement discussion. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau Technologies, Inc. (“Cerveau”), outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties’ execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims.

*CRG Litigation*

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company’s primary bank accounts and took possession of $4.1 million that was on deposit, applying $3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining $189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the $59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than $47 million and no more than $66 million. In addition, CRG agreed that Navidea had the right to assert all affirmative defenses to its claim of default. In the underlying case the district court had entered summary judgment in favor of CRG finding unspecified events of default but refusing to consider affirmative defenses raised by Navidea as not before the Court. Subsequent to the settlement CRG moved again for entry of judgment in its favor; Navidea objected that the Settlement Agreement specifically allowed it to raise affirmative defenses and the district court agreed with Navidea setting the case for trial in December 2017. CRG once again moved for summary judgment and the motion was heard by the Court on October 30, 2017. The Court did not indicate when it intends to rule on the motion. The trial is currently scheduled for December 11, 2017.

Concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a $7 million letter of credit in favor of CRG (at the Company’s cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414’s indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a $12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG’s letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of $59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The $2 million being held in escrow pursuant to court order in the Ohio case and the $3 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. The Texas hearing is currently set for early December 2017.

*Former CEO Arbitration*

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to certain provisions in Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez was seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In response, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez withdrew his claim for additional severance pursuant to his Employment Agreement, and the Company withdrew its counterclaims. On May 12, 2017, the Company received a ruling in favor of Mr. Gonzalez finding that he was terminated by the Company without cause on April 7, 2016. Mr. Gonzalez was awarded salary, bonus, and benefits in the aggregate amount of $481,039 plus interest, attorneys' fees, and other costs. The arbitration award is final and binding on the parties. The Company paid an aggregate of $617,880 to Mr. Gonzalez on May 16, 2017.

*FTI Consulting, Inc. Litigation*

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of $782,600 comprised of: (i) $730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement between FTI and the Company, and (ii) in excess of $52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. On June 26, 2017, the Company and FTI entered into a settlement agreement. According to FTI, as of June 2017, FTI was owed $862,165 including interest charges and legal fees. Under the terms of the settlement agreement, the Company paid an aggregate of $435,000 to FTI on June 30, 2017.

*Sinotau Litigation – Tc99m Tilmanocept*

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On July 12, 2017, the District of Delaware case was transferred to the Southern District of Ohio. On July 27, 2017 the Ohio Court determined that both cases in the Southern District of Ohio are related and the case was stayed for 60 days pending settlement discussions. Both cases remain open because all issues raised in the complaints have not been resolved but the parties have continued settlement discussions and the Court extended the stays in both cases.

*Platinum-Montaur Life Sciences LLC*

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of $1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement (discussed above). The Company has not yet been served with process in the action. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

**Item 1A. Risk Factors**

There have been no material changes to the Company's risk factors as previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 (the "Form 10-K"), filed with the SEC on March 31, 2017.

**Item 6. Exhibits**

| | |
|---|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 31.2 | Certification of Chief Operating Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 32.1 | Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.** |
| 32.2 | Certification of Chief Operating Officer and Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.** |
| 101.INS | XBRL Instance Document* |
| 101.SCH | XBRL Taxonomy Extension Schema Document* |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document* |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document* |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document* |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document* |

* Filed herewith.
** Furnished herewith.

***Items 2, 3, 4 and 5 are not applicable and have been omitted.***

**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.

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
November 9, 2017

By: /s/ Jed A. Latkin

Jed A. Latkin
Chief Operating Officer and Chief Financial Officer
(Authorized Officer; Principal Financial and Accounting Officer)

**INDEX TO EXHIBITS**

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* Filed herewith.
** Furnished herewith.

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael M. Golberg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Navidea Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2017

/s/ Michael M. Goldberg
Michael M. Goldberg, M.D.
President and Chief Executive Officer
(principal executive officer)

**Exhibit 31.2**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jed A. Latkin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Navidea Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2017

/s/ Jed A. Latkin
Jed A. Latkin
Chief Operating Officer and Chief Financial Officer
(principal financial and accounting officer)

**Exhibit 32.1**

**CERTIFICATION OF PERIODIC FINANCIAL REPORT PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002, 18 U.S.C. SECTION 1350**

The undersigned hereby certifies that he is the duly appointed and acting Chief Executive Officer of Navidea Biopharmaceuticals, Inc. (the "Company") and hereby further certifies as follows:

(1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned has executed and delivered this certificate as of the date set forth opposite his signature below.

November 9, 2017

/s/ Michael M. Goldberg
Michael M. Goldberg, M.D.
President and Chief Executive Officer
(principal executive officer)

**Exhibit 32.2**

**CERTIFICATION OF PERIODIC FINANCIAL REPORT PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002, 18 U.S.C. SECTION 1350**

The undersigned hereby certifies that he is the duly appointed and acting Chief Operating Officer and Chief Financial Officer of Navidea Biopharmaceuticals, Inc. (the "Company") and hereby further certifies as follows:

(1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned has executed and delivered this certificate as of the date set forth opposite his signature below.

November 9, 2017

/s/ Jed A. Latkin
Jed A. Latkin
Chief Operating Officer and Chief Financial Officer
(principal financial and accounting officer)