NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
November 09, 2018

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, 2018

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

For the transition period from _____ to _____

Commission File Number: 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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: 181,890,700 shares of common stock, par value $.001 per share (as of the close of business on November 1, 2018).

NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

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PART I – Financial Information

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

	September 30, 2018 (unaudited)	**December 31, 2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$5,707,465	$2,795,006
Available-for-sale securities	798,948	1,797,604
Accounts and other receivables	86,928	8,137,872
Prepaid expenses and other	547,027	1,101,923
Total current assets	7,140,368	13,832,405
Property and equipment	1,224,310	1,206,058
Less accumulated depreciation and amortization	1,059,132	969,357
Property and equipment, net	165,178	236,701
Patents, trademarks and license agreements	480,404	480,404
Less accumulated amortization	44,496	22,248
Patents, trademarks and license agreements, net	435,908	458,156
Guaranteed earnout receivable	—	4,809,376
Other assets	1,367,588	1,444,798
Total assets	$9,109,042	$20,781,436
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$615,524	$855,043
Accrued liabilities and other	2,950,140	1,857,848
Notes payable	2,164,330	2,353,639
Terminated lease liability, current	116,901	107,215
Accrued loss for CRG litigation	—	2,887,566
Liabilities associated with discontinued operations, current	—	7,092
Total current liabilities	5,846,895	8,068,403
Terminated lease liability	487,501	588,092

Deferred revenue	700,000	11,024
Other liabilities	64,583	65,587
Total liabilities	7,098,979	8,733,106
Commitments and contingencies (Note 11)		
Stockholders’ equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock; $.001 par value; 300,000,000 shares authorized; 181,890,700 and 162,206,646 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	181,891	162,207
Additional paid-in capital	334,723,420	331,128,787
Accumulated deficit	(333,562,563)	(319,908,968)
Accumulated other comprehensive loss	(1,052)	(2,396)
Total Navidea stockholders' equity	1,341,696	11,379,630
Noncontrolling interest	668,367	668,700
Total stockholders’ equity	2,010,063	12,048,330
Total liabilities and stockholders’ equity	$9,109,042	$20,781,436

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue:				
Tc99m tilmanocept royalty revenue	$2,382	$—	$9,842	$—
License revenue	19,930	—	277,639	100,000
Grant and other revenue	209,146	223,669	762,549	1,315,298
Total revenue	231,458	223,669	1,050,030	1,415,298
Cost of revenue	38,101	—	73,811	—
Gross profit	193,357	223,669	976,219	1,415,298
Operating expenses:				
Research and development	1,225,770	874,547	3,367,444	2,765,695
Selling, general and administrative	2,688,703	1,734,707	6,254,474	9,006,725
Total operating expenses	3,914,473	2,609,254	9,621,918	11,772,420
Loss from operations	(3,721,116)	(2,385,585)	(8,645,699)	(10,357,122)
Other (expense) income:				
Interest (expense) income, net	(28,074)	76,050	(20,234)	144,811
Change in fair value of financial instruments	—	—	—	153,357
Loss on extinguishment of debt	—	—	(4,265,434)	(1,314,102)
Other, net	3,540	(6,979)	1,654	(45,256)
Total other (expense) income, net	(24,534)	69,071	(4,284,014)	(1,061,190)
Loss before income taxes	(3,745,650)	(2,316,514)	(12,929,713)	(11,418,312)
(Provision for) benefit from income taxes	(76,259)	775,750	(65,330)	3,861,156
Loss from continuing operations	(3,821,909)	(1,540,764)	(12,995,043)	(7,557,156)
Discontinued operations, net of tax effect:				
Income (loss) from discontinued operations	—	5,399	(1,938)	(332,838)
Gain on sale	—	145,877	43,053	86,894,000
Net (loss) income	(3,821,909)	(1,389,488)	(12,953,928)	79,004,006
Less loss attributable to noncontrolling interest	(308)	(23)	(333)	(192)
Net (loss) income attributable to common stockholders	$(3,821,601)	$(1,389,465)	$(12,953,595)	$79,004,198
(Loss) income per common share (basic):				
Continuing operations	$(0.02)	$(0.01)	$(0.08)	$(0.05)
Discontinued operations	$—	$—	$—	$0.54
Attributable to common stockholders	$(0.02)	$(0.01)	$(0.08)	$0.49
Weighted average shares outstanding (basic)	166,855,420	162,006,646	163,963,940	161,437,276
(Loss) income per common share (diluted):				
Continuing operations	$(0.02)	$(0.01)	$(0.08)	$(0.05)

Discontinued operations	$—	$—	$—	$0.52
Attributable to common stockholders	$(0.02)	$(0.01)	$(0.08)	$0.47
Weighted average shares outstanding (diluted)	166,855,420	162,006,646	163,963,940	165,914,473

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Comprehensive (Loss) Income

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net (loss) income	$(3,821,909)	$(1,389,488)	$(12,953,928)	$79,004,006
Unrealized gain (loss) on available-for-sale securities	1,012	(172)	1,344	(1,200)
Comprehensive (loss) income	$(3,820,897)	$(1,389,660)	$(12,952,584)	$79,002,806

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statement of Stockholders' Equity

(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Compre-hensive Loss	Non-controlling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2018	162,206,646	$162,207	$331,128,787	$(319,908,968)	$ (2,396)	$668,700	$12,048,330
Impact of adoption of ASC Topic 606	—	—	—	(700,000)	—	—	(700,000)
Issued stock in payment of employee bonuses	1,118,760	1,118	315,784	—	—	—	316,902
Issued restricted stock	200,000	200	—	—	—	—	200
Cancelled forfeited restricted stock	(50,000)	(50)	50	—	—	—	—
Issued stock to 401(k) plan	94,684	95	35,885	—	—	—	35,980
Issued stock pursuant to private placement	18,320,610	18,321	2,981,679	—	—	—	3,000,000
Stock compensation expense	—	—	261,235	—	—	—	261,235
Comprehensive loss:							
Net loss	—	—	—	(12,953,595)	—	(333)	(12,953,928)
Unrealized gain on available-for-sale securities	—	—	—	—	1,344	—	1,344
Total comprehensive loss	—	—	—	—	—	—	(12,952,584)
Balance, September 30, 2018	181,890,700	$181,891	$334,723,420	$(333,562,563)	$ (1,052)	$668,367	$2,010,063

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net (loss) income	$(12,953,928)	$79,004,006
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	113,088	212,077
Loss on disposal and abandonment of assets	—	806,710
Compounded interest on long term debt	128,902	211,443
Stock compensation expense	261,235	319,807
Change in fair value of financial instruments	—	(153,357)
Loss on extinguishment of debt	4,265,434	1,314,102
Issued warrants in connection with Asset Sale	—	3,337,187
Value of stock issued to directors	—	10,500
Value of stock issued to employees	316,902	369,342
Value of stock issued to 401(k) plan for employer matching contributions	35,980	53,707
Changes in operating assets and liabilities:		
Accounts and other receivables	12,860,320	(12,686,071)
Inventory	—	1,470,826
Prepaid expenses and other assets	632,106	495,434
Accounts payable	(239,519)	(5,897,416)
Accrued and other liabilities	992,304	(5,507,487)
Deferred revenue	(10,037)	(2,315,037)
Net cash provided by operating activities	6,402,787	61,045,773
Cash flows from investing activities:		
Purchases of available-for-sale securities	(200,000)	(2,200,000)
Proceeds from sales of available-for-sale securities	200,000	—
Maturities of available-for-sale securities	1,000,000	200,000
Purchases of equipment	(19,317)	(31,417)
Net cash provided by (used in) investing activities	980,683	(2,031,417)
Cash flows from financing activities:		
Proceeds from issuance of common stock	3,000,200	54,319
Payment of debt-related costs	(7,153,000)	(1,314,102)
Principal payments on notes payable	(318,211)	(59,675,502)
Net cash used in financing activities	(4,471,011)	(60,935,285)
Net increase (decrease) in cash and cash equivalents	2,912,459	(1,920,929)

Cash and cash equivalents, beginning of period	2,795,006	6,540,578
Cash and cash equivalents, end of period	$5,707,465	$4,619,649

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, 2018 and for the three-month and nine-month periods ended September 30, 2018 and 2017 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 ("U.S. GAAP") 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, 2018 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, 2017, which were included as part of our Annual Report on Form 10-K.

In March 2017, the Company completed the sale to Cardinal Health 414, LLC ("Cardinal Health 414") of its assets used in developing, manufacturing and commercializing Lymphoseek® in North America. See Note 3. Following the sale to Cardinal Health 414, the Company is primarily focused on commercializing its Tc99m tilmanocept products in markets outside the U.S. and on developing additional products based on our Manocept™ platform.

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.

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.

Certain prior period amounts also have been reclassified to conform to the current year's presentation, including the adoption of Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers,* and cash flows related to loss on extinguishment of debt.

b. **Financial Instruments and Fair Value:** The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

(1) *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. At September 30, 2018 and December 31, 2017, approximately $96,000 of accounts payable was being disputed by the Company related to unauthorized expenditures by a former executive during 2016.

(2) *Notes payable:* The carrying value of our debt at September 30, 2018 and December 31, 2017 primarily consisted of the face amount of the notes less unamortized discounts. At September 30, 2018, the fair value of our notes payable was approximately $2.2 million, equal to the carrying value of $2.2 million. At December 31, 2017, the fair value of our notes payable was approximately $2.4 million, equal to the carrying value of $2.4 million. See Note 9.

(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, 2018 and December 31, 2017 are included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of September 30, 2018 and December 31, 2017 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 5.

(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 nine-month period ended September 30, 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 at the time of issuance. See Note 13.

c. **Recently Adopted Accounting Standards:** In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes 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. We adopted ASU 2014-09, along with additional related ASUs 2016-08, 2016-10, 2016-12 and 2016-20, effective January 1, 2018, using the modified retrospective method of adoption. The adoption of ASU 2014-09 and related ASUs resulted in increases in deferred revenue and accumulated deficit of $700,000. See Note 4.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows – Restricted Cash*. ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash or equivalents. Therefore, restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts ASU 2016-18 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. We adopted ASU 2016-18 effective January 1, 2018. The adoption of ASU 2016-18 resulted in reclassification of $5.0 million of restricted cash in the consolidated statement of cash flows for the nine-month period ended September 30, 2017.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740) – Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. ASU 2018-05 amends Accounting Standards Codification ("ASC") Topic 740 to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (the "Tax Act") pursuant to Staff Accounting Bulletin No. 118. ASU 2018-05 addresses situations where the accounting under ASC Topic 740 is incomplete for certain income tax effects of the Tax Act upon issuance of the entity's financial statements for the reporting period in which the Tax Act was enacted. The adoption of ASU 2018-05 in March 2018 did not have a material effect on our consolidated financial statements.

d. **Recently Issued Accounting Standards:** In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We have begun our assessment of the impact of adopting ASU 2016-02, and expect to complete that process during the fourth quarter of 2018. We expect the adoption of ASU 2016-02 to result in an increase in right-of-use assets and related liabilities of approximately $300,000 on our balance sheet related to our leases that are currently classified

as operating leases, primarily for office space.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards, and that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with Customers*. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of ASU 2018-07 is not expected to have a significant impact on our consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-09, *Codification Improvements*. ASU 2018-09 updates a variety of topics in order to clarify, correct errors, or make minor improvements to the Codification, making it easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. Certain amendments in ASU 2018-09 are effective upon issuance, others are effective for annual periods beginning after December 15, 2018 for public business entities, and some have been made to recently issued guidance and will be subject to the effective dates within the relevant guidance. The adoption of ASU 2018-09 is not expected to have a significant impact on our consolidated financial statements.

Also in July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU No. 2018-11, *Targeted Improvements to Topic 842, Leases*. ASU 2018-10 updates Topic 842 in order to clarify narrow aspects of the guidance issued in ASU 2016-02, *Leases (Topic 842)*. ASU 2018-11 provides entities with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, *Leases*). An entity that elects this transition method must prove the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments in ASU 2018-10 and ASU 2018-11 are effective when ASU 2016-02 is effective, for fiscal years beginning after December 15, 2018. We do not expect the adoption of ASU 2018-10 and ASU 2018-11 to have a significant impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements on fair value measurements in Topic 280, Fair Value Measurement, including the consideration of costs and benefits. ASU 2018-13 removes the requirements to disclose (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, (3) the valuation processes for Level 3 fair value measurements, and (4) for nonpublic entities, the changes in unrealized gains and losses for the period included in earnings for recurring Level 3 fair value measurements held at the end of the reporting period. ASU 2018-13 also modifies certain disclosure requirements as follows: (1) in lieu of a rollforward for Level 3 fair value measurements, a nonpublic entity is required to disclose transfers into and out of Level 3 and purchase and issuances of Level 3 assets and liabilities, (2) for investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly, and (3) the amendments clarify that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date. Finally, ASU 2018-13 adds the requirements to disclose (1) the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period, and (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. We do not expect the adoption of ASU 2018-13 to have any impact on our consolidated financial statements, however it may have an impact on our fair value disclosures.

2. Liquidity

As disclosed in the Company's Annual Report on Form 10-K and other filings, the Company is engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG"), and is currently pursuing recovery of $4.1 million and other damages. The Company was also engaged in litigation with Platinum-Montaur Life Sciences LLC ("Platinum-Montaur"), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P. ("PPVA"), Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, "Platinum"), in which Platinum-Montaur is seeking damages of

approximately $1.9 million plus interest. On October 31, 2018, the Court granted judgment for Navidea and dismissed all claims in the Platinum-Montaur case. See Notes 9 and 11.

Effective August 14, 2018, Dr. Michael Goldberg resigned as the Chief Executive Officer and President, and from the Board of Directors, of the Company. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into a binding agreement (the "Agreement"), with the intent of entering into one or more additional definitive agreements (the "Definitive Agreements"), that set forth the terms of the separation from service. The Agreement provides that Dr. Goldberg will be entitled to receive a severance of $978,000 payable in equal installments over two years, along with a one-time payment of approximately $35,000 which represents the cost of continuing his existing health care coverage for a period of 16 months. The Agreement also provides that Dr. Goldberg will be entitled to 23.5 million shares of common stock of Navidea, representing in part payment of accrued bonuses and payment of the balance of the Platinum Note. See Note 11.

On September 13, 2018, the Company entered into a Stock Purchase Agreement with an investor, pursuant to which the Company issued 18,320,610 shares of the Company's common stock in exchange for $3.0 million in cash (the "Private Placement"). The Company plans to use the proceeds from the Private Placement for general working capital purposes, including, without limitation, research and development, and other operating expenses. See Note 12.

The Company has experienced recent unfavorable court rulings and is currently still engaged in lawsuits with CRG. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. Our projected cash burn factors in certain cost cutting initiatives that have been approved by the Board of Directors and implemented, 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. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, based on our current working capital and our projected cash burn, and without definitive agreements in place for additional funding, management believes that there is substantial doubt about the Company's ability to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q.

3. Discontinued Operations

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 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 a License-Back Agreement 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").

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 additions to the purchase price) to the Company based on net sales derived from the purchased Product.

Upon closing of the Asset Sale, the Supply and Distribution Agreement dated November 15, 2007, as amended, 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).

On April 2, 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit. This was in addition to the $4.1 million and the $59.0 million that Navidea had previously 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 million 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. We recorded an additional gain related to the Amendment to the Asset Purchase Agreement of $43,000 for the nine months ended September 30, 2018, including $54,000 of additional consideration, offset by $11,000 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 liabilities have been segregated and included in liabilities associated with discontinued operations, as appropriate, in the consolidated balance sheets:

	September 30, 2018	**December 31, 2017**
Accrued liabilities	$ —	$ 7,092
Liabilities associated with discontinued operations, current	$ —	$ 7,092

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,	
	2018	2017	2018	2017
Lymphoseek sales revenue	$—	$—	$—	$2,917,213
Cost of goods sold	—	—	—	364,192
Gross profit	—	—	—	2,553,021
Operating expenses:				
Research and development	—	(5,951)	2,453	382,070
Selling, general and administrative	—	—	—	805,464
Total operating expenses	—	(5,951)	2,453	1,187,534
(Loss) income from discontinued operations	—	5,951	(2,453)	1,365,487
Interest expense	—	—	—	(1,718,506)
(Loss) income before income taxes	—	5,951	(2,453)	(353,019)
Benefit from (provision for) income taxes	—	(552)	515	20,181
(Loss) income from discontinued operations	$—	$5,399	$(1,938)	$(332,838)

4. Revenue from Contracts with Customers

The Company adopted ASU 2014-09, along with all subsequent related ASUs impacting revenue from contracts with customers (collectively, “the new revenue recognition standard”), effective January 1, 2018, using the modified retrospective method of adoption. The Company has applied the new revenue recognition standard for the three-month and nine-month periods ended September 30, 2018 with the cumulative effect of initially applying the new accounting recognized on January 1, 2018 as an adjustment to opening accumulated deficit. This adjustment reflects only contracts that were not completed as of January 1, 2018.

We earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. The new revenue recognition standard generally results in the delay of revenue recognition for the Company, as compared to the previous guidance. Previously, the Company recognized revenue related to non-refundable up-front license fees either immediately upon contract execution, or over the estimated period required to fulfill the related obligations. Under the new revenue recognition standard, the Company will generally be required to defer any up-front license fees and

pre-market milestones, and recognize the revenue over the period beginning with initial product sale through the end of the initial term of the agreement.

The cumulative effect of the change on accumulated deficit as of January 1, 2018 is an increase of $700,000, consisting of $100,000 related to an up-front payment received upon execution of an exclusive license and distribution agreement with Sayre Pharmaceuticals ("Sayre") for the development and commercialization of Tc99m tilmanocept in India in June 2017, and $600,000 related to up-front and milestone payments received pursuant to an exclusive licensing and distribution agreement with Beijing Sinotau Medical Research Co., Ltd. ("Sinotau") for the marketing and distribution of Tc99m tilmanocept in China executed in August 2014. The following table compares deferred revenue as if the new revenue recognition standard had not been adopted to the amounts in the consolidated financial statements reflecting the adoption. Deferred revenue, the current portion of which is included in accrued liabilities and other in the consolidated balance sheets, and accumulated deficit are the only financial statement line items that were affected by the adoption of the new revenue recognition standard.

	Pre-Adoption	**Post-Adoption**	**Change**
Deferred revenue	$26,061	$726,061	$700,000
Accumulated deficit	(319,908,968)	(320,608,968)	(700,000)

During the three-month and nine-month periods ended September 30, 2018, the Company recognized revenue from contracts with customers of approximately $22,000 and $287,000, respectively. The Company did not recognize any related impairment losses during those periods.

Navidea is focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. 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, and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by MT. Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, is the only one of the Company's drug product candidates that has been approved for sale in any market. The Company has license and distribution agreements in place in Europe, India and China, however Tc99 tilmanocept has only been approved for sale in Europe.

In April 2018, the Company executed an agreement to provide Meilleur Technologies, Inc., ("Meilleur"), a wholly-owned subsidiary of Cerveau Technologies, Inc. ("Cerveau"), worldwide rights to conduct research using NAV4694, as well as an exclusive license for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore. Meilleur also has an option to commercialize worldwide.

The following tables disaggregate the Company's revenue from contracts with customers for the three-month and nine-month periods ended September 30, 2018.

Three Months Ended September 30, 2018	**Diagnostics**	**Therapeutics**	**Total**
Tc99m tilmanocept royalty revenue:			
Europe	$ 2,382	$ —	$2,382
India	—	—	—
China	—	—	—
Total	$ 2,382	$ —	$2,382
License revenue:			
NAV4694 sublicense	$ 14,930	$ —	$14,930
Tc99m tilmanocept sublicense, China	5,000	—	5,000
Total	$ 19,930	$ —	$19,930
Other revenue:			
Additional stability studies	$ —	$ —	$—

Nine Months Ended September 30, 2018	**Diagnostics**	**Therapeutics**	**Total**
Tc99m tilmanocept royalty revenue:			
Europe	$ 9,842	$ —	$9,842
India	—	—	—
China	—	—	—
Total	$ 9,842	$ —	$9,842
License revenue:			
NAV4694 sublicense	$ 272,639	$ —	$272,639
Tc99m tilmanocept sublicense, China	5,000	—	5,000
Total	$ 277,639	$ —	$277,639
Other revenue:			
Additional stability studies	$ 15,037	$ —	$15,037

The following economic factors affect the nature, amount, timing and uncertainty of the Company's revenue and cash flows as indicated:

Geographical Location of Customers: Drug pricing models vary among different markets, which in turn may affect the royalty rates and milestones we are able to negotiate with our distributors in those markets. Royalty rates and milestone payments vary by contract but may be based in part on the potential market size in each territory. Royalty rates for Europe are lower than rates in India but higher than in China.

Status of Regulatory Approval: The majority of revenue from contracts with customers will generally be recognized after the product is approved for sale in each market. Each customer operates in its own distinct regulatory environment, and the laws and pathways to drug product approval vary by market. Tc99m tilmanocept has been approved for sale in Europe, thus the Company has begun to recognize royalties from sales in Europe. Tc99m tilmanocept has not yet been approved for sale in India or China, and may never achieve approval in those markets. The regulatory pathways and timelines in those markets will impact whether and when the Company recognizes the related royalties and milestones.

The following table summarizes the changes in contract liabilities, the current portion of which is included in accrued liabilities and other in the consolidated balance sheets, during the three-month and nine-month periods ended September 30, 2018 and 2017:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Total deferred revenue, beginning of period	$721,024	$26,061	$26,061	$41,098
Impact of adoption of ASU 2014-09 and related standards	—	—	700,000	—
Revenue deferred related to sublicense	—	—	10,000	—
Revenue recognized from satisfaction of performance obligations	(5,000)	—	(20,037)	(15,037)
Total deferred revenue, end of period	$716,024	$26,061	$716,024	$26,061

Currently, the Company recognizes revenue from up-front license fees and pre-market milestones after the cash has been received from its customers and the performance obligations have been met. Payments for sales-based royalties and milestones are generally received after the related revenue has been recognized and invoiced. Normal payment terms generally range from 15 to 90 days following milestone achievement or royalty invoice, in accordance with each contract. The Company had trade receivables of approximately $10,000 outstanding as of September 30, 2018.

During the three-month and nine-month periods ended September 30, 2018, the Company did not recognize any revenue from performance obligations associated with long-term contracts that were satisfied (or partially satisfied) in previous periods.

Up-front and milestone payments received related to our license and distribution agreements in India and China are deferred until Tc99m tilmanocept has been approved by the regulatory authorities in each of those countries. It is not possible to determine with any degree of certainty whether or when regulatory approval for this product will be achieved in India or China, if at all. In addition, since sales of Tc99m tilmanocept have not yet begun in India or China, there is no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Therefore, it is not possible to determine with any degree of certainty the expected sales in future periods in those countries. As such, the Company intends to recognize revenue from up-front and milestone payments on a straight-line basis beginning at the time of regulatory approval in each country through the end of the initial term of each agreement. The initial term of each agreement is eight years in India and 10 years in China.

The transaction price of a contract is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. Transaction prices do not include amounts collected on behalf of third parties (e.g., sales taxes). To determine the transaction price of a contract, the Company considers the terms of the contract. For the purpose of determining transaction prices, the Company assumes that the

goods or services will be transferred to the customer as promised in accordance with existing contracts and that the contracts will not be cancelled, renewed, or modified.

When estimating a contract's transaction price, the Company considers all the information (historical, current, and forecasted) that is reasonably available to it and identifies possible consideration amounts. Most of the Company's contracts with customers include both fixed and variable components of the transaction price. Under those contracts, some or all of the consideration for satisfied performance obligations is contingent on events over which the Company has no direct influence. For example, regulatory approval or product sales volume milestones are contingent upon the achievement of those milestones by the distributor. Additionally, the prices charged to end users of Tc99m tilmanocept, upon which royalty payments are based in Europe, India and China, are set by the distributor in each of those countries.

The milestone payments have a binary outcome (that is, the Company will either receive all or none of each milestone payment) and can be estimated using the most-likely-amount method. Taking into account the constraint on variable consideration, the Company has assessed the likelihood of achieving the non-sales-based milestone payments in our contracts and has determined that it is probable the milestones will be achieved and the Company will receive the consideration. Accordingly, it is probable that including those payments in the transaction price will not result in a significant revenue reversal when the contingency is resolved. Therefore, the amount of the non-sales-based milestone payments is included in the transaction price.

Royalties are estimated based on the expected value method because they are based on a variable amount of sales representing a range of possible outcomes. However, when taking into account the constraint on variable consideration, the estimate of future royalties included in the transaction price is generally $0. This conclusion is based on the fact that Tc99m tilmanocept is early in the commercial launch process in Europe and sales have not yet begun in India or China, therefore there is currently no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Similarly, we currently have no basis for estimating whether sales-based milestones will ever be achieved. Accordingly, the Company recognizes revenue from royalties when the related sales occur and from sales-based milestones when they are achieved.

The sublicense of NAV4694 to Meilleur provides for payments to Navidea including up-front payments, milestones, an option for worldwide commercial rights, royalties on net sales, and reimbursement for product development assistance during the initial transition period. In accordance with the new revenue recognition standard, the upfront payments were recognized upon contract inception, and reimbursement for product development assistance will be recognized on a monthly basis. Should some or all of the variable consideration from milestones, the option and royalties meet the requirements of the new revenue recognition standard to be included in the transaction price, those amounts will be recognized as revenue in future periods.

Up-front fees, milestones and royalties are generally non-refundable. Therefore, the Company does not estimate expected refunds nor do we adjust revenue downward. The Company will evaluate and update the estimated transaction prices of its contracts with customers at the end of each reporting period.

Through September 30, 2018, the Company has not capitalized any contract-related costs as contract assets.

5. Fair Value

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, 2018 and December 31, 2017, is included in other liabilities on the accompanying consolidated balance sheets, and will continue to be measured on a recurring basis. See Note 1(b).

The following table sets 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, 2018 and December 31, 2017

Description	**Quoted Prices in Active Markets for Identical Liabilities**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**

	(Level 1)			
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.

b. **Sensitivity Analysis-Level 3 Measurements:** Changes in the valuation of MT as a whole may cause material changes in the fair value of the MT warrants. Significant increases (decreases) in the valuation of MT, such as may be the result of additional financing, could result in a higher (lower) fair value measurement. A change in the valuation of MT would not necessarily result in a directionally similar change in the value of the MT warrants.

There were no Level 1 or Level 2 liabilities outstanding at any time during the three-month and nine-month periods ended September 30, 2018 and 2017. 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, 2018 and 2017. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses), if any, 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, 2018 and 2017 was $0 in both periods. The change in the estimated fair value of our Level 3 liabilities during the nine-month periods ended September 30, 2018 and 2017 was $0 and a decrease of $153,000, respectively.

6. Stock-Based Compensation

For the three-month periods ended September 30, 2018 and 2017, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $44,000 and $64,000, respectively. For the nine-month periods ended September 30, 2018 and 2017, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $261,000 and $320,000, 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, 2018 and 2017.

A summary of the status of our stock options as of September 30, 2018, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2018			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at beginning of period	3,687,679	$ 1.50		
Granted	470,000	0.53		
Exercised	—	—		
Canceled and Forfeited	(116,000)	0.71		
Expired	(7,000)	0.66		
Outstanding at end of period	4,034,679	$ 1.41	6.3	$ —
Exercisable at end of period	2,260,683	$ 2.00	4.3	$ —

A summary of the status of our unvested restricted stock as of September 30, 2018, and changes during the nine-month period then ended, is presented below:

	Nine Months Ended September 30, 2018	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	150,000	$ 0.51
Granted	200,000	0.37
Vested	(200,000)	0.47
Forfeited	(50,000)	0.36
Unvested at end of period	100,000	$ 0.37

As of September 30, 2018, there was approximately $101,000 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 1.2 years.

7. (Loss) Earnings Per Share

Basic (loss) earnings per share is calculated by dividing net (loss) income 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 (loss) earnings 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 (loss) earnings per share for the three-month and nine-month periods ended September 30, 2018 and 2017:

	Three Months Ended		**Nine Months Ended**	
	September 30,		**September 30,**	
	2018	**2017**	**2018**	**2017**
Weighted average shares outstanding, basic	166,855,420	162,006,646	163,963,940	161,437,276
Dilutive shares related to warrants	—	—	—	4,277,197
Unvested restricted stock	—	—	—	200,000
Weighted average shares outstanding, diluted	166,855,420	162,006,646	163,963,940	165,914,473

Diluted (loss) earnings per common share for the nine-month periods ended September 30, 2018 and 2017 excludes the effects of 18.6 million and 15.1 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, 100,000 and 200,000 shares of unvested restricted stock for the nine-month periods ended September 30, 2018 and 2017, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

8. Accounts Payable, Accrued Liabilities and Other

At September 30, 2018, approximately $96,000 of accounts payable is being disputed by the Company related to unauthorized expenditures by a former executive during 2016.

Accrued liabilities and other at September 30, 2018 and December 31, 2017 includes an aggregate of $2.3 million and $975,000, respectively, due to related parties for accrued termination costs, bonuses and director fees.

9. Notes Payable

Platinum-Montaur Life Sciences LLC

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 Platinum Partners Capital Opportunity Fund L.P. ("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 were transferred by Platinum-Montaur to PPCO. See Note 11.

During the nine-month periods ended September 30, 2018 and 2017, $129,000 and $211,000 of interest was compounded and added to the balance of the Platinum Note, respectively. Of the interest compounded during the nine

months ended September 30, 2017, $143,000 of interest expense was reclassified to discontinued operations. As of September 30, 2018, the remaining outstanding principal balance of the Platinum Note was approximately $2.2 million.

The Platinum Note is reflected on the consolidated balance sheets at its estimated fair value, which includes the estimated fair value of the embedded conversion option of $0 at September 30, 2018 and December 31, 2017. Changes in the estimated fair value of the Platinum Note were $0 during both of the three-month periods ended September 30, 2018 and 2017. Changes in the estimated fair value of the Platinum Note were $0 and a decrease of $153,000, respectively, and were recorded as non-cash changes in fair value of the conversion option during the nine-month periods ended September 30, 2018 and 2017. The estimated fair value of the Platinum Note was $2.2 million and $2.0 million as of September 30, 2018 and December 31, 2017, respectively.

Capital Royalty Partners II, L.P.

In May 2015, Navidea and MT, as guarantor, executed a Term Loan Agreement (the “CRG Loan Agreement”) with 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 $50.0 million (the “CRG Term Loan”). On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid $59.0 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan.

As disclosed in the Company’s Annual Report on Form 10-K and other filings, the Company has been engaged in ongoing litigation with CRG in the District Court of Harris County, Texas (the “Texas Court”). Following a trial in December 2017, the Texas Court ruled that the Company’s total obligation to CRG was in excess of $66.0 million, limited to $66.0 million under the Global Settlement Agreement. The Texas Court acknowledged only the $59.0 million payment made in March 2017, concluding that the Company owed CRG another $7.0 million, however the Texas Court did not expressly take the Company’s June 2016 payment of $4.1 million into account and awarded, as part of the $66.0 million, amounts that had already been paid as part of the $4.1 million. In April 2018, CRG drew approximately $7.1 million on a letter of credit that was established pursuant to the Global Settlement Agreement. This was in addition to the $4.1 million and the $59.0 million that Navidea had previously paid to CRG. The Company believes that the $4.1 million should be credited against the $7.0 million and is currently pursuing recovery of $4.1 million and other damages. See Note 11.

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 made in July 2017.

In November 2017, we prepaid $396,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 4.0%. The note was payable in ten monthly installments of $40,000, with the final payment made in August 2018. The balance of the note was approximately $0 and $318,000 as of September 30, 2018 and December 31, 2017, respectively, and was included in notes payable, current in the consolidated balance sheets.

Summary

During the three-month periods ended September 30, 2018 and 2017, we recorded interest expense of $45,000 and $26,000, respectively, related to our notes payable. Of these amounts, $44,000 and $29,000 was compounded and added to the balance of our notes payable during the three-month periods ended September 30, 2018 and 2017, respectively. During the nine-month periods ended September 30, 2018 and 2017, we recorded interest expense of $134,000 and $91,000, respectively, related to our notes payable. Of these amounts, $129,000 and $68,000 was compounded and added to the balance of our notes payable during the nine-month periods ended September 30, 2018 and 2017, respectively.

10. 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 for the Blazer space (the "Sublease") 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 initially recorded a total liability of $1.0 million, which was 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 $399,000 and a loss on disposal of assets, primarily leasehold improvements and

furniture and fixtures, related to the Blazer space of $706,000. Both losses were included in selling, general and administrative expenses for the year ended December 31, 2017.

A summary of the changes in our terminated lease liability during the nine-month period ended September 30, 2018 is presented below:

	Terminated Lease Liability
Total liability, January 1, 2018	$ 695,307
Changes in estimated future payments	(43,393)
Payments under Blazer lease	(349,290)
Receipts from subtenant	273,869
Accretion of liability	27,909
Total liability, September 30, 2018	$ 604,402

11. 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, 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. In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and the parties have filed multiple joint motions to stay the case pending settlement discussion, which to date have been granted.

In October 2017, the Company executed a letter of intent with Sinotau and 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 included 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.

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In April 2018, the Company executed an agreement to provide Meilleur worldwide rights to conduct research using NAV4694, as well as an exclusive license for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore. Meilleur also has an option to commercialize worldwide. As a result of the agreement, the litigation initiated by Sinotau was dismissed in September 2018.

CRG Litigation

As disclosed in the Company's Annual Report on Form 10-K and other filings, the Company has been engaged in ongoing litigation with CRG, in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement, in the Texas Court relating to CRG's claims of default under the terms the CRG Loan Agreement. Following a trial in December 2017, the Texas Court ruled that the Company's total obligation to CRG was in excess of $66.0 million, limited to $66.0 million under the parties' Global Settlement Agreement reached in 2017. The Texas Court acknowledged only the $59.0 million payment made in March 2017, concluding that the Company owed CRG another $7.0 million, however the Texas Court did not expressly take the Company's June 2016 payment of $4.1 million into account and awarded, as part of the $66.0 million, amounts that had already been paid as part of the $4.1 million. The Company believes that this $4.1 million should be credited against the $7.0 million; CRG disagrees.

On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the double recovery created by the $66.0 million award without taking into account the $4.1 million payment in June 2016, requesting that the judgment be modified to set the supersedeas amount at $2.9 million so that the Company could stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. On March 26, 2018, the Texas Court ordered the Company to put up a supersedeas bond in the amount of $7.7 million. The Company filed for an emergency stay of the order in the appellate court in Harris County. On April 2, 2018, the appellate court denied the Company's emergency stay motion. The Company continues to believe that the $4.1 million paid to CRG in June 2016 should be credited as payment toward the $66.0 million total, and the Company intends to further contest the matter through the appellate court in Texas. The Company filed its initial brief on the merits in this appeal on October 1, 2018 with CRG filing its response on October 31, 2018. Navidea's final reply brief is due on November 20, 2018. The Company does not expect a ruling on this appeal until 2019 at the earliest.

On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit. This was in addition to the $4.1 million and the $59.0 million that Navidea had previously paid to CRG.

On April 12, 2018 Navidea filed suit in the Ohio Court against the Lenders. The suit asserts that the Lenders fraudulently induced Navidea to enter into a settlement agreement and breached the terms of the same through certain actions taken by the Lenders in connection with the Global Settlement Agreement reached in 2017, pursuant to which Navidea agreed to pay up to $66.0 million to Lenders, as well as through actions and misrepresentations by CRG after

the Global Settlement Agreement was executed. The suit also asserts claims for conversion and unjust enrichment against the Lenders for their collection of more than $66.0 million, the maximum permitted under the Global Settlement Agreement, and their double recovery of amounts paid as part of the $4.1 million paid in June 2016 and recovered again as part of the $66.0 million. CRG's double recovery and recovery of more than $66.0 million are due to CRG drawing the entire $7.1 million on the Cardinal Health 414 letter of credit. On May 22, 2018 Navidea filed an amended complaint asserting additional claims, including claims for breach of confidentiality by CRG, and on June 26, 2018 CRG filed a motion seeking to dismiss the amended complaint. On August 16, 2018, the Court entered an Order granting in part and overruling in part CRG's Motion to Dismiss. While several of the Company's claims were dismissed, the core of the Complaint, relating to the claimed $4.1million overpayment to CRG was permitted to proceed. On August 27, 2018, CRG filed a Petition with the Ohio Supreme Court seeking a Writ of Prohibition against the Trial court and asserting that the Trial Court's denial in part of CRG's Motion to Dismiss was improper. The Petition has been fully briefed and a decision is expected in the near future. At the Trial Court level, discovery is ongoing in the case and it is anticipated that the Company will file a Motion for Summary Judgment sometime in 2019.

In a related proceeding before the Ohio Court, initially filed in 2016, and under which the Global Settlement Agreement was reached in 2017, the Ohio Court has issued preliminary findings that the settlement gave rise to a $66.0 million cap on amounts owed to Lenders by Navidea and that Navidea might not have been properly credited for certain funds in excess of $4.1 million previously swept by Lenders from a bank account owned by Navidea. The Ohio Court also made a preliminary ruling that it possessed jurisdiction to interpret the settlement agreement at issue. The Company is pursuing recovery of the $4.1 million, and other damages, in the Ohio Court.

On April 11, 2018, CRG filed a new suit against the Company in the Texas Court. This new suit seeks a declaratory judgment that CRG did not breach the Global Settlement Agreement by drawing approximately $7.1 million on the Cardinal Health 414 letter of credit. On April 16, 2018, CRG moved the Texas Court to issue an anti-suit injunction barring the Company from litigating in the Ohio Court. The Texas Court denied that motion on April 27, 2018. The Company moved to dismiss these claims pursuant to the Texas Citizens Participation Act. On August 17, 2018, the Texas Court denied the Company's Motion to Dismiss. That same day, the Company took an immediate appeal of its claims under the Texas Citizens Participation Act to the Fourteenth Court of Appeals of Texas. The Company filed its initial brief on the merits in this appeal on October 23, 2018 with CRG's response due on November 12, 2018. The Company does not expect a ruling on this appeal until 2019 at the earliest.

On July 11, 2018, CRG filed a first amended petition in the new suit. This amended petition includes the prior request for declaratory judgment that CRG did not breach the Global Settlement Agreement. In addition, the amended petition asserts a claim against Navidea for breach of contract. CRG alleges that Navidea breached the Global Settlement Agreement and its duty of good faith and fair dealing by seeking reconsideration in the original Texas suit, appealing the original Texas suit, and filing the Ohio suit. The Company is contesting this issue in the Ohio Court, the Texas Court, and on appeal in Texas. See Notes 2 and 9.

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. On February 8, 2018, Navidea and Sinotau executed an amendment to the agreement, modifying certain terms of the agreement and effectively resolving the legal dispute. On February 17, 2018, Navidea and Sinotau executed a Settlement Agreement and Mutual Release, and on February 20, 2018, Navidea and Sinotau voluntarily dismissed their legal cases.

Platinum-Montaur Litigation

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 of approximately $1.9 million purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted were for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. Said action was removed to the United States District Court for the Southern District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018 and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss was due on April 6, 2018. The Company filed its motion to dismiss in advance of the filing deadline. On October 31, 2018, the Court granted judgment for Navidea and dismissed all claims in the case. The Court stated that Platinum-Montaur had no standing to assert any contractual interest in funds that might be due under the Platinum Loan Agreement. The Court also disagreed with Platinum-Montaur's claim of unjust enrichment on similar grounds and found that Platinum-Montaur lacked any sufficient personal stake to maintain claims against Navidea. The claims against Navidea were dismissed without prejudice on the grounds of lack of standing to pursue the claims asserted.

Goldberg Agreement

Effective August 14, 2018, Dr. Michael Goldberg resigned as the Chief Executive Officer and President, and from the Board of Directors, of the Company. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into a binding Agreement, with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of the separation from service. The Agreement provides that Dr. Goldberg will be entitled to

receive a severance of $978,000 payable in equal installments over two years, along with a one-time payment of approximately $35,000 which represents the cost of continuing his existing health care coverage for a period of 16 months. The Agreement also provides that Dr. Goldberg will be entitled to 23.5 million shares of common stock of Navidea, representing in part payment of accrued bonuses and payment of the balance of the Platinum Note. A portion of the 23.5 million shares to be issued to Dr. Goldberg will be held in escrow for up to 18 months in order to reimburse Navidea in the event that Navidea is obligated to pay any portion of the Platinum Note to a party other than Dr. Goldberg. Further, the Agreement provides that the Company's subsidiary, MT, will redeem all of Dr. Goldberg's preferred stock and issue to Dr. Goldberg super voting common stock equal to 5% of the outstanding shares of MT.

As of the date of filing this Quarterly Report on Form 10-Q, the Definitive Agreements have not yet been signed as negotiations are ongoing and the terms are subject to change. Any issuance of shares to Dr. Goldberg will be subject to NYSE American regulations. None of the 23.5 million shares of Navidea common stock have been issued, nor have the MT preferred shares been exchanged for MT super voting common stock.

NYSE American Continued Listing Standards

On August 14, 2018, the Company received a notification (the "Deficiency Letter") from the NYSE American stating that Navidea was not in compliance with certain NYSE American continued listing standards relating to stockholders' equity. Specifically, the Deficiency Letter stated that Navidea is not in compliance with Section 1003(a)(ii) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $4.0 million or more if it has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. The Deficiency Letter noted that Navidea had stockholders' equity of $2.1 million as of June 30, 2018, and has reported net losses in four of its five most recent fiscal years ended December 31, 2017.

Navidea was required to submit a plan to the NYSE American by September 14, 2018 advising of actions it has taken or will take to regain compliance with the continued listing standards by February 14, 2020. Navidea submitted a plan by the deadline.

On October 25, 2018, the Company received a notification (the "Acceptance Letter") from the NYSE American that the Company's plan to regain compliance was accepted. The Acceptance Letter also stated that the NYSE American had inadvertently omitted an additional deficiency from the Deficiency Letter. Specifically, the Deficiency Letter should have stated that Navidea is not in compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years. The Acceptance Letter noted that Navidea had stockholders' equity of $2.1 million as of June 30, 2018, and has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2017.

The Company must provide quarterly updates to the NYSE American staff (the "Staff") concurrent with its interim/annual SEC filings. If Navidea fails to regain compliance with the stockholders' equity standards by February

14, 2020, the NYSE American may commence delisting procedures.

In addition, the Deficiency Letter stated that the Staff determined that the Company's securities have been selling for a low price per share for a substantial period of time and, pursuant to Section 1003(f)(v) of the NYSE American Company Guide, Navidea's continued listing is predicated on it effecting a reverse stock split of its common stock, par value $0.001 per share ("Common Stock") or otherwise demonstrating sustained price improvement within a reasonable period of time, which the Staff has determined to be no later than February 14, 2019. Navidea must regain compliance with the price standard by that date in order to be considered for continued trading through the end of February 14, 2020.

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. Although the outcome of any litigation is uncertain, in our opinion, the amount of ultimate liability, if any, with respect to these actions, will not materially affect our financial position.

12. Equity Instruments

During September 2018, the Company entered into a Stock Purchase Agreement with an investor, pursuant to which the Company issued to the investor in a private placement (the "Private Placement") 18,320,610 shares (the "Securities") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at a purchase price of $3.0 million (the "Purchase Price"). The Company plans to use the proceeds from the Private Placement for general working capital purposes, including, without limitation, research and development, and other operating expenses.

During the nine-month periods ended September 30, 2018 and 2017, we issued 1,118,760 and 710,353 shares of our common stock valued at $317,000 and $369,000, respectively, to our employees as payments in lieu of cash for their 2017, 2016 and 2015 bonuses.

During the nine-month periods ended September 30, 2018 and 2017, we issued 94,684 and 105,308 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $36,000 and $54,000, respectively.

During the nine-month period ended September 30, 2017, we issued 16,406 shares of our common stock valued at $10,500 to certain members of our Board of Directors as payment in lieu of cash for their retainer fees. We did not make any such stock payments to our directors during the nine-month period ended September 30, 2018.

13. Stock Warrants

In January 2017, Dr. Michael Goldberg, then 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 Series NN 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 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 nine-month period ended September 30, 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 nine-month period ended September 30, 2017.

At September 30, 2018, there are 16.4 million warrants outstanding to purchase Navidea's common stock. The warrants are exercisable at prices ranging from $0.01 to $2.50 per share with a weighted average exercise price of $1.15 per share. The warrants have remaining outstanding terms ranging from one to 17 years.

In addition, at September 30, 2018, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at $2,000 per share.

14. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets (“DTAs”) and deferred tax liabilities (“DTLs”) 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. DTAs and DTLs 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 DTAs and DTLs of a change in tax rates is recognized in income in the period that includes the enactment date.

Current accounting standards require a valuation allowance against DTAs if, based on the weight of available evidence, it is more likely than not that some or all of the DTAs may not be realized. Due to the uncertainty surrounding the realization of these DTAs in future tax returns, all of the DTAs have been fully offset by a valuation allowance at September 30, 2018 and December 31, 2017, except the alternative minimum tax (“AMT”) credit carryforward amount described below.

In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax-planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the DTAs are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of September 30, 2018 except for the AMT credit carryforward.

The Tax Cuts and Jobs Act (the "Tax Act") was signed into law on December 22, 2017. The Tax Act reduced the U.S. federal corporate tax rate from 35% to 21%, effective January 1, 2018. The Tax Act repeals the AMT for corporations, and permits any existing AMT credit carryforwards to be used to reduce the regular tax obligation in 2018, 2019 and 2020. Companies may continue using AMT credits to offset any regular income tax liability in years 2018 through 2020, with 50 percent of remaining AMT credits refunded for each of the 2018, 2019 and 2020 tax years, and all remaining credits refunded in tax year 2021. This results in full realization of an existing AMT credit carryforward irrespective of future taxable income. However, as the refund is subject to a sequestration reduction rate of approximately 6.2%, we established a federal DTA valuation allowance of approximately $76,000 during the nine-month period ending September 30, 2018. Accordingly, net AMT credit carryforwards of $1.1 million and $1.2 million are reflected in other noncurrent assets in the consolidated balance sheets as of September 30, 2018 and December 31, 2017, respectively. The impact of many provisions of the Tax Act lack clarity and is subject to interpretation until additional IRS guidance is issued. The ultimate impact of the Tax Act may differ from the Company's estimates due to changes in the interpretations and assumptions made as well as any forthcoming regulatory guidance.

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, 2018 or December 31, 2017 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, 2018, tax years 2014-2017 remained subject to examination by federal and state tax authorities.

Provision for income taxes was $76,000 for the three-month period ended September 30, 2018, representing the sequestration of a portion of our AMT credit carryforwards and an effective tax rate of 2.0%. Benefit from income taxes was $776,000 for the three-month period ended September 30, 2017, representing an effective tax rate of 34.0%. The decrease in the effective rate for the three-month period ended September 30, 2018 compared with the same period in 2017 is primarily due to the corporate rate reduction of the Tax Act.

As of September 30, 2018, we had approximately $131.8 million of federal and $20.4 million of state net operating loss carryforwards, as well as approximately $9.7 million of federal R&D credit carryforwards.

15. 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, and NAV4694 (sublicensed in April 2018), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by MT.

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

Three Months Ended September 30, 2018	**Diagnostics**	**Therapeutics**	**Corporate**	**Total**
Royalty revenue	$ 2,382	$ —	$—	$2,382
License revenue	19,930	—	—	19,930
Grant and other revenue	65,505	143,641	—	209,146
Total revenue	87,817	143,641	—	231,458
Cost of revenue	38,101	—	—	38,101
Research and development expenses	711,355	514,415	—	1,225,770
Selling, general and administrative expenses, excluding depreciation and amortization [1]	—	20,532	2,630,581	2,651,113
Depreciation and amortization [2]	—	—	37,590	37,590
Loss from operations [3]	(661,639)	(391,306)	(2,668,171)	(3,721,116)
Other expense [4]	—	—	(24,534)	(24,534)
Income tax expense	(10,081)	(3,879)	(62,299)	(76,259)
Net loss from continuing operations	(671,720)	(395,185)	(2,755,004)	(3,821,909)
Net loss	(671,720)	(395,185)	(2,755,004)	(3,821,909)
Total assets, net of depreciation and amortization:				
United States	$ 117,722	$ 72,622	$8,899,301	$9,089,645
International	18,239	—	1,158	19,397
Capital expenditures	—	—	16,152	16,152

Three Months Ended September 30, 2017	Diagnostics	Therapeutics	Corporate	Total
Grant and other revenue	$210,479	$ 13,190	$—	$223,669
Research and development expenses	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	—	—	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

Nine Months Ended September 30, 2018	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$9,842	$ —	$—	$9,842
License revenue	277,639	—	—	277,639
Grant and other revenue	454,830	307,719	—	762,549
Total revenue	742,311	307,719	—	1,050,030
Cost of revenue	73,811	—	—	73,811
Research and development expenses	2,409,524	957,920	—	3,367,444
Selling, general and administrative expenses, excluding depreciation and amortization [1]	—	45,769	6,095,617	6,141,386
Depreciation and amortization [2]	—	—	113,088	113,088
Loss from operations [3]	(1,741,024)	(695,970)	(6,208,705)	(8,645,699)
Other expense [4]	—	—	(4,284,014)	(4,284,014)
Income tax expense	(8,797)	(3,517)	(53,017)	(65,330)
Net loss from continuing operations	(1,749,821)	(699,487)	(10,545,736)	(12,995,043)
Loss from discontinued operations, net of tax	(1,938)	—	—	(1,938)
Gain on sale of discontinued operations, net of tax	43,053	—	—	43,053
Net loss	(1,708,706)	(699,487)	(10,545,736)	(12,953,928)
Total assets, net of depreciation and amortization:				
United States	$117,722	$ 72,622	$8,899,301	$9,089,645
International	18,239	—	1,158	19,397
Capital expenditures	—	—	19,317	19,317

Nine Months Ended September 30, 2017	Diagnostics	Therapeutics	Corporate	Total
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
Research and development expenses	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 expense [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

(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 ($37,590 and $50,326 for the three-month periods ended September 30, 2018 and 2017, and $113,088 and $197,655 for the nine-month periods ended September 30, 2018 and 2017, 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, other than those expenses directly incurred by MT.

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

16. Supplemental Disclosure for Statements of Cash Flows

During the nine-month periods ended September 30, 2018 and 2017, we paid interest aggregating $8,000 and $7.4 million, respectively. During the nine-month periods ended September 30, 2018 and 2017, we issued 94,684 and 105,308 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $36,000 and $54,000, respectively. During the nine-month period ended September 30, 2017, we issued 1.0 million Series NN warrants to UCSD with an estimated fair value of $334,000.

17. Subsequent Events

The Company has evaluated events and transactions subsequent to September 30, 2018 and through the date these consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the U.S. Securities and Exchange Commission (“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:

- our history of operating losses and uncertainty of future profitability;
- 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 programs;
- our dependence on royalties and grant revenue;
- our limited product line and distribution channels;
- advances in technologies and development of new competitive products;
- our ability to maintain effective control over financial reporting;

our ability to comply with NYSE American continued listing standards; 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,” “estimate,” “proje 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., a Delaware corporation (NYSE American: 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 undetected 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 Tc99m tilmanocept, 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 Company completed its previously announced 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 (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company). 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.

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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 another 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 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.

Upon closing of the Asset Sale, the Supply and Distribution Agreement dated November 15, 2007, as amended, 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).

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.

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 and NAV4694, and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by MT. See Note 15 to the consolidated financial statements for more information about our business segments.

Product Line Overview

Our primary development efforts over the last several years were focused on diagnostic products, including Lymphoseek which was sold to Cardinal Health 414 in March 2017. Our more recent initiatives have been focused exclusively on diagnostic and therapeutic line extensions based on our Manocept platform.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed primarily on activated macrophages. This flexible and versatile platform serves as a molecular engine for purpose-built targeted imaging molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This CD206-targeted drug platform is 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, as well as delivery of therapeutic compounds that target macrophages, and their role in a variety of immune- and inflammation-involved diseases. 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 and to expand this technology into additional diagnostic and therapeutic applications.

Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. 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 rheumatoid arthritis ("RA"), atherosclerosis/vulnerable plaque, nonalcoholic steatohepatitis ("NASH"), inflammatory bowel disease, systemic lupus erythematosus, Kaposi's sarcoma ("KS"), leishmaniosis, and others that span general clinical areas in oncology, autoimmunity, infectious diseases, cardiology, CNS diseases, and inflammation. For the near term, we have selected target diseases that may, if successfully developed, benefit from this remarkable technology, most deriving improved clinical diagnosis and therapy.

Manocept Platform – Immuno-Diagnostics Clinical Data

Rheumatoid Arthritis

Two Tc99m tilmanocept dose escalation studies in RA have been completed. The first study was completed and included 18 subjects (nine with active disease and nine healthy subjects) dosed subcutaneously with 50 and 200 µg/2mCi Tc99m tilmanocept (ClinicalTrials.gov NCT02683421). The results of this study were presented at five international meetings, including Biotechnology Innovation Organization ("BIO"), Society of Nuclear Medicine and Molecular Imaging ("SNMMI"), and The American College of Rheumatology ("ACR"). In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have completed a study involving intravenous ("IV") dosing of 39 subjects with IV-administered Tc99m tilmanocept (ClinicalTrials.gov NCT02865434). In conjunction with this study, we have completed pharmacokinetic, pharmacodynamics and radiation dosimetry phases in human subjects as well. The majority of the costs of these studies have been supported through a Small Business Innovation Research ("SBIR") grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1). Results were presented at the June 2018 SNMMI meeting. These studies have been combined and submitted for peer review publication and full published results will follow.

Cardiovascular Disease ("CV")

In collaboration with researchers at Massachusetts General Hospital, Navidea has completed one and initiated a second clinical study evaluating Tc99m tilmanocept's ability to enable imaging of atherosclerotic plaques. Results of these studies provide strong preliminary evidence of the potential of Tc99m tilmanocept to accumulate specifically in and enable imaging of non-calcified atherosclerotic plaques. Non-calcified atherosclerotic plaques include plaques with morphologies indicating a high risk of rupture. Rupture of such plaques causes myocardial infarctions (heart attacks) and a significant portion of ischemic strokes. The studies compared aortic Tc99m tilmanocept uptake imaged by SPECT/CT in clinically asymptomatic subjects with intermediate Framingham Risk Scores ("FRS") who were infected with Human Immunodeficiency Virus ("HIV") as compared to healthy, uninfected, FRS and age-matched subjects. Tc99m tilmanocept SPECT/CT images were compared to aortic images of the same subjects obtained by contrast enhanced coronary computed tomography angiography and/or [18F]NaF PET/CT.

A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed subcutaneously is complete (ClinicalTrials.gov NCT02542371). The results of this study were presented at two major international meetings (Conference on Retroviruses and Opportunistic Infections ("CROI") and SNMMI, 2017) and published in early release in the *Journal of Infectious Diseases* in January 2017 (published in the circulated version, *Journal of Infectious Diseases* (2017) **215** (8): 1264-1269), confirming that the Tc99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch of Acquired Immunodeficiency Syndrome ("AIDS") patients (supported by NIH/NHLBI Grant 1 R43 HL127846-01).

We have also begun a second Phase1/2 study in cooperation with Massachusetts General Hospital in subjects with HIV that expands the original study in both the scope of the drug administration as well as the diagnostic assessment of the subjects. This study will enroll up to 24 AIDS subjects and healthy controls in imaging non-calcified plaque using IV-administered Tc99m tilmanocept and will expand the initial investigation to the assessment of aortic plaque as well as carotid and coronary arteries. Initial images from this study are currently being evaluated.

Kaposi's Sarcoma

KS is a serious and potentially life-threatening illness, which in the US occurs disproportionately in persons infected with HIV and in organ transplant patients. The prognosis for patients with treatment resistant KS is poor with high probabilities for mortality and greatly diminished quality of life. We initiated and completed a study of KS in 2015 (ClinicalTrials.gov NCT022201420), and received additional funding from the National Institutes of Health ("NIH") in 2016 to continue diagnostic 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). This now-escalated study includes a pathology/biopsy component as well as an imaging component to determine pathology concordance with image assessment. We received Institutional Review Board approval of the clinical protocol, and we initiated a Phase 1/2 clinical study in KS in 2017.

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 supported through a SBIR grant (NIH/NCI 1 R44 CA1962783-01A1; ClinicalTrials.gov NCT03029988) and continues to enroll subjects (up to 12 subjects with dose modification; this study may also be expanded depending on NIH/NCI funding). An initial presentation took place at SNMMI in June of 2018. An additional report has been submitted to the National Cancer Institute ("NCI") on the early results of this study.

Nonalcoholic Steatohepatitis

We have initiated a clinical study (ClinicalTrials.gov NCT03332940) that is designed to enroll 12 subjects with IV administration of Tc99m tilmanocept and an imaging comparator to identify and quantify the extent of NASH lesions in human patients. This study is ongoing and includes dose escalation modification for Tc99m tilmanocept. Initial results were presented at the NASH Summit in Boston in April 2018, and the results are available on Navidea's website. This study continues to enroll patients.

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Biomarker Application and Qualification

In November 2017, the Company commenced the qualification of the biomarker CD206 with the FDA Biomarker Section of The Center for Drug Evaluation and Research ("CDER"). As per FDA protocol, Navidea submitted a draft letter of intent ("LOI") to CDER prior to the November meeting. According to the CDER directive, "the Biomarker Qualification Program was established to support the CDER's work with external stakeholders to develop biomarkers that aid in the drug development process. Through the FDA's Biomarker Qualification Program, an entity may request regulatory qualification of a biomarker for a particular context of use ("COU") in drug development." Post-meeting with the FDA and because of Navidea's data sets and the general external publication database, Navidea, in conjunction with FDA, is now reviewing the LOI with the FDA's recommended consultants. Navidea has revised the LOI draft strategy in order to expedite the application process. In March 2018, Navidea had a follow-up meeting with the FDA's assigned strategist and further narrowing of the LOI elements were reviewed. Navidea is continuing the process of finalizing the COU LOI and providing the background data sets for qualification review with the FDA/CDER. Additional meetings have taken place and the pursuit of this qualification is progressing well.

Macrophage Therapeutics Background

In December 2014, the Company formed a new business unit to further explore therapeutic applications for the Manocept platform. In January 2015, Navidea incorporated the business unit as MT, a majority-owned subsidiary of Navidea. Navidea also granted MT an exclusive license for certain therapeutic applications of the Manocept technology. In August 2018, the Company entered into an Agreement with Dr. Michael Goldberg related to his resignation from Navidea. The Agreement provides that MT will redeem all of Dr. Goldberg's MT preferred stock and issue to Dr. Goldberg MT super voting common stock equal to 5% of the outstanding shares of MT. As of the date of filing this Quarterly Report on Form 10-Q, the Definitive Agreements have not yet been signed and the MT preferred shares have not yet been exchanged for MT super voting common stock. See Note 11 to the accompanying consolidated financial statements.

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

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 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, we continue this work funded by the NIH/NIAID and NCI. The Company has completed preclinical studies employing both MT 1000-class and 2000-class therapeutic conjugates of Manocept. The positive results from these studies are indicative of Manocept's specific targeting supported by its strong binding affinity to CD206 receptors. This high degree of 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.

Kaposi's Sarcoma

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. We have received additional funding to continue therapeutic studies in this disease 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, now complete, supported analyses including *in vitro* and cell culture studies, to be followed by Parts 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 (supported by NIH/NCI 1 R44 CA206788-01).

Nonalcoholic Fatty Liver Disease ("NAFLD")

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. We 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 interfering more broadly with the normal function of the immune system.

We have completed five *in vivo* studies employing our MT-1002 and MT-2002 Manocept conjugates in a 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™ 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.

Other Immunotherapeutic Applications

We have 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 published in the *Journal of Experimental Medicine (*published in the circulated version *Journal of Experimental Medicine* 2018 Jan 2;215(1):357-375). 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.

The Company continues 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.

NAV4694 (Sublicensed)

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. Discussions related to the potential partnering or divestiture of NAV4694 were delayed due in large part to litigation brought by Sinotau, one of the potential partners. In August 2015, 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. In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and the parties have filed multiple joint motions to stay the case pending settlement discussion, which to date have been granted.

In October 2017, the Company executed a letter of intent with Sinotau and 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 included 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. In April 2018, the Company executed an agreement to provide Meilleur, a wholly-owned subsidiary of Cerveau, worldwide rights to conduct research using NAV4694, as well as an exclusive license for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore. Meilleur also has an option to commercialize worldwide. As a result of the agreement, the litigation initiated by Sinotau was dismissed in September 2018. See Note 11 to the accompanying consolidated financial statements.

Outlook

Our operating expenses in recent years have been focused primarily on support of our Manocept platform, Tc99m tilmanocept, and NAV4694 product development. We incurred approximately $3.4 million and $2.8 million in total on research and development activities during the nine-month periods ended September 30, 2018 and 2017, 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]	**2018**	**2017**
Manocept Platform [b]	$906,178	$1,034,380
Macrophage Therapeutics [b]	1,063,992	610,921
Tc99m Tilmanocept [c]	143,928	187,829
NAV4694 [d]	19,105	(399,146)

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $763,000 and $1.3 million during the nine-month periods ended September 30, 2018 and 2017, respectively.
(b) Certain 2017 amounts have been reclassified from Manocept Platform to Macrophage Therapeutics to conform to 2018 presentation.
(c) Amounts in 2017 reflect projects included in discontinued operations in the consolidated statements of operations.
(d) Changes in cost estimates resulted in the reversal of certain previously accrued expenses related to the NAV4694 development program 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 2018 and into 2019. We expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be higher in 2018 than in 2017. The suspension of active patient accrual in our NAV4694 trials have decreased our development costs related to that program over the past year, however, we may continue to incur minimal costs while we complete our divestiture activities with Meilleur.

Tc99m tilmanocept is approved by the European Medicines Agency 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. 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, disease-staging and treatment of disorders in which macrophages are involved, such as KS, RA, NASH and other disease states, to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. We will also be 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 of obtaining funding or other resources on terms acceptable to us, if at all, 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 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 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG.

In April 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. CRG has drawn the entire $7.1 million available under the letter of credit.

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 million 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. We recorded an additional gain related to the Amendment to the Asset Purchase Agreement of $43,000 for the nine months ended September 30, 2018, including $54,000 of additional consideration, offset by $11,000 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 Business as a discontinued operation as 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, 2018 and 2017

Royalty Revenue. During the third quarter of 2018, we recognized royalty revenue of $2,000 related to our license agreement with SpePharm in Europe. No royalty revenue was recognized during the third quarter of 2017.

License Revenue. During the third quarter of 2018, we recognized license revenue of $20,000, primarily for activities related to the sublicense of NAV4694 to Meilleur and the sublicense of Tc99m tilmanocept to Sinotau. No license revenue was recognized during the third quarter of 2017.

Grant and Other Revenue. During the third quarter of 2018, we recognized $209,000 of grant and other revenue as compared to $224,000 in the third quarter of 2017. Grant revenue during the third quarters of 2018 and 2017 was primarily related to SBIR grants from the NIH supporting Manocept development.

Research and Development Expenses. Research and development expenses increased $351,000, or 40%, to $1.2 million during the third quarter of 2018 from $875,000 during the same period in 2017. The increase was primarily due to net increases in drug project expenses related to (i) increased therapeutics development costs of $331,000 including increased research consulting costs and manufacturing-related activities; offset by (ii) decreased NAV4694 development costs of $70,000 including decreased clinical trial costs offset by increased manufacturing-related activities; (iii) decreased Manocept development costs of $20,000, primarily decreased clinical trial costs; and (iv) decreased Tc99m tilmanocept development costs of $13,000, primarily decreased manufacturing-related activities. The net increase in research and development expenses also included increased compensation including incentive-based awards of $63,000 and increased general office and travel expenses totaling $37,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $954,000, or 55%, to $2.7 million during the third quarter of 2018 from $1.7 million during the same period in 2017. The net increase was primarily due to increased compensation including incentive-based awards of $1.2 million, including termination costs associated with the resignation of our former CEO, Michael Goldberg, of $1.1 million, coupled with an increase in investor relations costs, primarily related to the annual stockholders meeting, of $24,000. These increases were offset by decreased legal and professional services of $181,000 and decreased general office, depreciation, and rent expenses totaling $107,000.

Other Income (Expense). Other expense, net, was $25,000 during the third quarter of 2018 as compared to other income, net of $69,000 during the same period in 2017. During the third quarters of 2018 and 2017, $44,000 and $29,000, respectively, of interest expense was compounded and added to the balance of our note payable to Platinum. During the third quarters of 2018 and 2017, we recorded interest income of $17,000 and $102,000, respectively. Of the interest income recorded during the third quarter of 2017, $88,000 was related to the guaranteed consideration due from Cardinal Health 414, which was discounted to present value at the closing date of the Asset Sale.

Nine Months Ended September 30, 2018 and 2017

Royalty Revenue. During the first nine months of 2018, we recognized royalty revenue of $10,000 related to our license agreement with SpePharm in Europe. No royalty revenue was recognized during the first nine months of 2017.

License Revenue. During the first nine months of 2018, we recognized license revenue of $278,000, primarily for a non-refundable upfront payment related to the sublicense of NAV4694 to Meilleur and the sublicense of Tc99m tilmanocept to Sinotau. 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.

Grant and Other Revenue. During the first nine months of 2018, we recognized $763,000 of grant and other revenue as compared to $1.3 million in the same period in 2017. Grant revenue during the first nine months of 2018 was primarily related to SBIR grants from the NIH supporting Manocept development. Grant revenue during the first nine months of 2017 was primarily related to SBIR grants from the NIH supporting Manocept and Tc99m tilmanocept development. Other revenue for the first nine months of 2018 and 2017 included $82,000 and $34,000, 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 increased $602,000, or 22%, to $3.4 million during the first nine months of 2018 from $2.8 million during the same period in 2017. The increase was primarily due to net increases in drug project expenses related to (i) increased therapeutics development costs of $453,000 including increased research consulting, regulatory consulting, and preclinical testing, offset by decreased manufacturing-related activities; and (ii) increased NAV4694 development costs of $418,000 due to reversal of certain previously accrued expenses during the first nine months of 2017, offset by increased clinical testing; offset by (iii) decreased Manocept development costs of $128,000, primarily decreased clinical trial costs; and (iv) decreased Tc99m tilmanocept development costs of $44,000 including decreased manufacturing-related activities, clinical testing, and license fees, offset by increased regulatory costs. The net increase in research and development expenses also included decreased compensation including incentive-based awards of $197,000 related to net decreased headcount offset by increased general office and travel expenses totaling $71,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $2.7 million, or 31%, to $6.3 million during the first nine months of 2018 from $9.0 million during the same period in 2017. The net decrease was primarily due to decreased legal and professional services of $2.0 million, a loss on disposal of assets related to our previous office space of $717,000, termination costs related to the arbitration award to Mr. Gonzalez of $478,000 and loss on termination of our previous office lease of $472,000, both during the first nine months of 2017, and decreased general office, insurance, depreciation, rent, and travel expenses totaling $384,000. The net decrease in selling, general and administrative expenses also included termination costs related to the resignation of Dr. Goldberg of $1.1 million.

Other Income (Expense). Other expense, net, was $4.3 million during the first nine months of 2018 as compared to other expense, net of $1.1 million during the same period in 2017. We recorded losses on extinguishment of the CRG debt of $4.3 million and $1.3 million during the first nine months of 2018 and 2017, respectively. Also during the first nine months of 2018 and 2017, we recognized interest income of $113,000 and $236,000, respectively, 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 in 2017. During the first nine months of 2018 and 2017, $129,000 and $68,000, respectively, of interest expense was compounded and added to the balance of our note payable to Platinum. For the first nine months of 2017, we recorded non-cash income of $153,000 related to changes in the estimated fair value of financial instruments.

Gain on Discontinued Operations. We recorded a net gain related to the Amendment to the sale of the Business to Cardinal Health 414 of $43,000 for the nine months ended September 30, 2018, including $54,000 of payments by Cardinal Health 414 to Navidea in excess of receivables recognized, offset by $11,000 in estimated taxes. We recorded a net gain on the sale of the Business to Cardinal Health 414 of $86.9 million for the nine months ended September 30, 2017, including $16.5 million 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. Operating losses from discontinued operations related to the sale of the Business to Cardinal Health 414 were $2,000 and $333,000 for the first nine months of 2018 and 2017, respectively.

Liquidity and Capital Resources

Cash balances increased to $5.7 million at September 30, 2018 from $2.8 million at December 31, 2017. The net increase was primarily due to accelerated receipt of the guaranteed earnout receivable from Cardinal Health 414 of $5.7 million, net of CRG’s draw on the letter of credit, proceeds from a private equity placement of $3.0 million, and maturities and sales of available-for-sale securities of $1.2 million, offset by cash used to fund our operations of $6.5 million.

Operating Activities. Cash provided by operations was $6.4 million during the first nine months of 2018 compared to $61.0 million during the same period in 2017.

Accounts and other receivables decreased to $87,000 at September 30, 2018 from $8.1 million at December 31, 2017, primarily related to Cardinal Health 414's payment of the entire balance of the guaranteed earnout pursuant to the Amendment executed on April 2, 2018.

Prepaid expenses and other current assets decreased to $547,000 at September 30, 2018 from $1.1 million at December 31, 2017. The decrease was primarily due to normal amortization of prepaid insurance and decreased interest receivable related to the guaranteed earnout due from Cardinal Health 414.

Accounts payable decreased to $616,000 at September 30, 2018 from $855,000 at December 31, 2017, primarily driven by net decreased payables due to NAV4694, therapeutics, and operations vendors, offset by increased payables due to Manocept development vendors. Accrued liabilities and other current liabilities increased to $3.0 million at September 30, 2018 from $1.9 million at December 31, 2017. Increased accruals for termination of Dr. Goldberg and incentive-based compensation were offset by decreases in accruals for legal and professional services. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we work to resolve our legal disputes, offset by planned increases in development activity related to the Manocept platform.

Investing Activities. Investing activities provided $981,000 during the first nine months of 2018 compared to $2.0 million used during the same period in 2017. Investing activities during the first nine months of 2018 included maturities and sales of available-for-sale securities of $1.2 million and capital expenditures of $19,000, primarily for research and computer equipment. 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.

Financing Activities. Financing activities used $4.5 million during the first nine months of 2018 compared to $60.9 million during the same period in 2017. The $4.5 million used by financing activities in the first nine months of 2018 consisted primarily of CRG's draw on the letter of credit of $7.1 million and principal payments on financed insurance premiums of $318,000, offset by proceeds from a private equity placement of $3.0 million. The $60.9 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 and payment of CRG debt-related costs to CRG of $1.3 million, offset by proceeds from issuance of common stock of $54,000.

Private Placement

On September 13, 2018, the Company entered into a Stock Purchase Agreement with an investor, pursuant to which the Company issued 18,320,610 shares of the Company's common stock in exchange for $3.0 million in cash. The Company plans to use the proceeds from the Private Placement for general working capital purposes, including, without limitation, research and development, and other operating expenses.

Cardinal Health 414 Asset Sale

On April 2, 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit.

Platinum Credit Facility

See Notes 9 and 11 to the accompanying consolidated financial statements.

Capital Royalty Group Debt

See Notes 9 and 11 to the accompanying consolidated financial statements.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including 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.

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We plan to focus our resources for the remainder of 2018 and into 2019 primarily on 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 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 financing if we cannot achieve that objective in a timely manner.

We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. If we attempt to raise additional capital through debt, royalty, equity or otherwise, we may not be successful in doing so on terms acceptable to the Company, if at all. Further, we may not be able to gain access and/or be able to secure new sources of funding, identify 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.

The Company has experienced recent unfavorable court rulings and is currently still engaged in lawsuits with CRG. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. Our projected cash burn factors in certain cost cutting initiatives that have been approved by the Board of Directors and implemented, 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. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, based on our current working capital and our projected cash burn, and without definitive agreements in place for additional funding, management believes that there is substantial doubt about the Company’s ability to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q. See Note 2 to the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

As of September 30, 2018, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Notes 1(c) and 1(d) to the accompanying 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 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 requires separate assessment in accordance with current accounting standards.

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 U.S. GAAP 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 included an embedded conversion option which was required to be recorded at fair value. The estimated fair value of the embedded conversion option was calculated using a probability-weighted 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 embedded conversion option 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, 2018, our $5.7 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, 2018, 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, 2018 was 6.0%). Based on the amount of our variable-rate borrowings at September 30, 2018, which totaled approximately $2.2 million, an immediate one percentage point increase (decrease) in the U.S. prime rate would increase (decrease) our annual interest expense by approximately $22,000. 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.

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, 2018 and 2017, we recorded foreign currency transaction gains (losses) of approximately $2,000 and ($39,000), 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 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, 2018, 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, 2018, and concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. 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.

Our management, including our Chief Executive Officer, 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, a 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

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. GAAP 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.

Changes in Control Over Financial Reporting

During the quarter ended September 30, 2018, there were no 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

See Note 11 to the accompanying consolidated financial statements.

Item 1A. Risk Factors

Except as set forth below, 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, 2017 (the "Form 10-K"), filed with the SEC on March 15, 2018.

Our failure to maintain continued compliance with the listing requirements of the NYSE American exchange could result in the delisting of our common stock.

Our common stock has been listed on the NYSE American since February 2011. The rules of NYSE American provide that shares be delisted from trading in the event the financial condition and/or operating results of the Company appear to be unsatisfactory, the extent of public distribution or the aggregate market value of the common stock has become so reduced as to make further dealings on the NYSE American inadvisable, the Company has sold or otherwise disposed of its principal operating assets, or has ceased to be an operating company, or the Company has failed to comply with its listing agreements with the Exchange. For example, the NYSE American may consider suspending trading in, or removing the listing of, securities of an issuer that has stockholders' equity of less than (i) $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years, (ii) $4.0 million if such issuer has sustained losses from continuing operations and/or net losses in three of its four most recent fiscal years, and (iii) $2.0 million if such issuer has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years. As of September 30, 2018, the Company had stockholders' equity of approximately $1.3 million. In addition, the Company had stockholders' deficits for several years prior to December 31, 2017, and we may not be able to maintain stockholders' equity in the future. Even if an issuer has a stockholders' deficit, the NYSE American will not normally consider delisting securities of an issuer that fails to meet these requirements if the issuer has (1) average global market capitalization of at least $50,000,000; or total assets and revenue of $50,000,000 in its last fiscal year, or in two of its last three fiscal years; and (2) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least $15,000,000 and 400 round lot shareholders. As of September 30, 2018, the Company's total value of market capitalization was approximately $35,000,000. As such, we do not currently meet these exceptions and there is a risk that our common stock may be

delisted as a result of our failure to meet the minimum stockholders' equity requirement for continued listing. The NYSE American provides for an 18-month “cure period” for the Company to regain the minimum stockholders’ equity requirement, however if the Company is unable to do so, the NYSE American may delist the Company’s common stock.

The NYSE American Company Guide also provides that the Exchange may suspend or remove from listing any common stock selling for a substantial period of time at a low price per share, if the issuer shall fail to effect a reverse split of such shares within a reasonable time after being notified that the Exchange deems such action to be appropriate under all the circumstances. The Company’s common stock has recently traded for a price as low as $0.13 per share, and if the low trading price persists, there is a risk that the Exchange may require the Company to effect a reverse split of its common stock in order to maintain its NYSE American listing.

On August 14, 2018, the Company received a Deficiency Letter from the NYSE American stating that Navidea was not in compliance with certain NYSE American continued listing standards relating to stockholders’ equity. Specifically, the Deficiency Letter stated that Navidea is not in compliance with Section 1003(a)(ii) of the NYSE American Company Guide, which requires an issuer to have stockholders’ equity of $4.0 million or more if it has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. The Deficiency Letter noted that Navidea had stockholders’ equity of $2.1 million as of June 30, 2018, and has reported net losses in four of its five most recent fiscal years ended December 31, 2017.

Navidea was required to submit a plan to the NYSE American by September 14, 2018 advising of actions it has taken or will take to regain compliance with the continued listing standards by February 14, 2020. Navidea submitted a plan by the deadline.

On October 25, 2018, the Company received an Acceptance Letter from the NYSE American that the Company’s plan to regain compliance was accepted. The Acceptance Letter also stated that the NYSE American had inadvertently omitted an additional deficiency from the Deficiency Letter. Specifically, the Deficiency Letter should have stated that Navidea is not in compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires an issuer to have stockholders’ equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years. The Acceptance Letter noted that Navidea had stockholders’ equity of $2.1 million as of June 30, 2018, and has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2017.

The Company must provide quarterly updates to the NYSE American Staff concurrent with its interim/annual SEC filings. If Navidea fails to regain compliance with the stockholders’ equity standards by February 14, 2020, the NYSE American may commence delisting procedures.

In addition, the Deficiency Letter stated that the Staff determined that the Company’s securities have been selling for a low price per share for a substantial period of time and, pursuant to Section 1003(f)(v) of the NYSE American

Company Guide, Navidea's continued listing is predicated on it effecting a reverse stock split of its Common Stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the Staff has determined to be no later than February 14, 2019. Navidea must regain compliance with the price standard by that date in order to be considered for continued trading through the end of February 14, 2020.

At the Company's 2018 Annual Meeting of Stockholders (the "Annual Meeting"), held on August 16, 2018, stockholders approved a reverse stock split of the Company's common stock, as determined by the Board of Directors at its discretion, of a ratio of not less than one-for-five and not more than one-for-twenty. The Board of Directors has not taken action to effect a reverse stock split as of the date of filing this Quarterly Report on Form 10-Q. There can be no assurance that the Board of Directors will take steps to implement the reverse stock split, and if they do, such a reverse stock split may not be sufficient to enable the Company to maintain its listing on the NYSE American. Therefore, there is a continued risk that the shares will be delisted if action is not taken to the satisfaction of the NYSE American.

Navidea's Common Stock will continue to be listed on the NYSE American while it attempts to regain compliance with the listing standards noted above, subject to Navidea's compliance with other continued listing requirements. The Common Stock will continue to trade under the symbol "NAVB," but will have an added designation of ".BC" to indicate that Navidea is not in compliance with the NYSE American's listing standards. The NYSE American notification does not affect Navidea's business operations or its SEC reporting requirements and does not conflict with or cause an event of default under any of Navidea's material agreements.

The delisting of our common stock from the NYSE American likely would reduce the trading volume and liquidity in our common stock and may lead to decreases in the trading price of our common stock. The delisting of our common stock may also materially impair our stockholders' ability to buy and sell shares of our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital.

Item 6. Exhibits

10.1	Agreement dated August 14, 2018, by and among Navidea Biopharmaceuticals, Inc., Macrophage Therapeutics, Inc. and Michael M. Goldberg, M.D.*
10.2	Stock Purchase Agreement dated September 13, 2018, by and between Navidea Biopharmaceuticals, Inc. and John K. Scott, Jr.*
10.3	Employment Agreement, effective October 1, 2018, by and between Navidea Biopharmaceuticals, Inc. and Jed A. Latkin (incorporated by reference to the Current Report on Form 8-K filed by the Company on October 5, 2018).
10.4	Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (as amended and restate on August 16, 2018) (incorporated by reference to the Current Report on Form 8-K filed by the Company on August 21, 2018).
31.1	Certification of Chief Executive Officer, 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, 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.

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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, 2018

By: /s/ Jed A. Latkin

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

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