NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-Q
August 08, 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 June 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging Growth Company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 163,620,090 shares of common stock, par value $.001 per share (as of the close of business on August 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

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$4,690,973	$2,795,006
Available-for-sale securities	797,936	1,797,604
Accounts and other receivables	373,876	8,137,872
Prepaid expenses and other	737,336	1,101,923
Total current assets	6,600,121	13,832,405
Property and equipment	1,208,158	1,206,058
Less accumulated depreciation and amortization	1,028,958	969,357
Property and equipment, net	179,200	236,701
Patents, trademarks and license agreements	480,404	480,404
Less accumulated amortization	37,080	22,248
Patents, trademarks and license agreements, net	443,324	458,156
Guaranteed earnout receivable	—	4,809,376
Other assets	1,437,847	1,444,798
Total assets	$8,660,492	$20,781,436
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$453,720	$855,043
Accrued liabilities and other	1,835,037	1,857,848
Notes payable	2,200,353	2,353,639
Terminated lease liability, current	139,833	107,215
Accrued loss for CRG litigation	—	2,887,566
Liabilities associated with discontinued operations, current	—	7,092
Total current liabilities	4,628,943	8,068,403
Terminated lease liability	479,566	588,092
Deferred revenue	700,000	11,024
Other liabilities	65,111	65,587
Total liabilities	5,873,620	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 June 30, 2018 and December 31, 2017	—	—
Common stock; $.001 par value; 300,000,000 shares authorized; 163,620,090 and 162,206,646 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	163,620	162,207
Additional paid-in capital	331,697,603	331,128,787
Accumulated deficit	(329,740,962)	(319,908,968)
Accumulated other comprehensive loss	(2,064)	(2,396)
Total Navidea stockholders' equity	2,118,197	11,379,630
Noncontrolling interest	668,675	668,700
Total stockholders’ equity	2,786,872	12,048,330
Total liabilities and stockholders’ equity	$8,660,492	$20,781,436

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2018	**2017**	**June 30, 2018**	**2017**
Revenue:				
Tc99m tilmanocept royalty revenue	$6,665	$—	$7,460	$—
License revenue	257,709	100,000	257,709	100,000
Grant and other revenue	277,753	511,599	553,403	1,091,629
Total revenue	542,127	611,599	818,572	1,191,629
Cost of revenue	35,392	—	35,710	—
Gross profit	506,735	611,599	782,862	1,191,629
Operating expenses:				
Research and development	1,142,718	1,185,874	2,141,674	1,891,148
Selling, general and administrative	1,789,399	4,249,584	3,565,771	7,272,018
Total operating expenses	2,932,117	5,435,458	5,707,445	9,163,166
Loss from operations	(2,425,382)	(4,823,859)	(4,924,583)	(7,971,537)
Other (expense) income:				
Interest (expense) income, net	(23,547)	44,649	7,840	68,761
Change in fair value of financial instruments	—	12,872	—	153,357
Loss on extinguishment of debt	—	—	(4,265,434)	(1,314,102)
Other, net	2,828	(16,673)	(1,886)	(38,277)
Total other (expense) income, net	(20,719)	40,848	(4,259,480)	(1,130,261)
Loss before income taxes	(2,446,101)	(4,783,011)	(9,184,063)	(9,101,798)
Benefit from income taxes	10,929	1,631,234	10,929	3,085,406
Loss from continuing operations	(2,435,172)	(3,151,777)	(9,173,134)	(6,016,392)
Discontinued operations, net of tax effect:				
Loss from discontinued operations	(1,938)	(82,376)	(1,938)	(338,237)
Gain (loss) on sale	43,053	(1,953,378)	43,053	86,748,123
Net (loss) income	(2,394,057)	(5,187,531)	(9,132,019)	80,393,494
Less (loss) income attributable to noncontrolling interest	(16)	33	(25)	(169)
Net (loss) income attributable to common stockholders	$(2,394,041)	$(5,187,564)	$(9,131,994)	$80,393,663
(Loss) income per common share (basic):				
Continuing operations	$(0.02)	$(0.02)	$(0.06)	$(0.04)
Discontinued operations	$—	$(0.01)	$—	$0.54
Attributable to common stockholders	$(0.02)	$(0.03)	$(0.06)	$0.50
Weighted average shares outstanding (basic)	162,716,988	161,910,792	162,494,238	161,147,873
(Loss) income per common share (diluted):				

Continuing operations	$(0.02)	$(0.02)	$(0.06)	$(0.04)
Discontinued operations	$—	$(0.01)	$—	$0.52
Attributable to common stockholders	$(0.02)	$(0.03)	$(0.06)	$0.49
Weighted average shares outstanding (diluted)	162,716,988	161,910,792	162,494,238	165,631,000

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Comprehensive (Loss) Income

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Net (loss) income	$(2,394,057)	$(5,187,531)	$(9,132,019)	$80,393,494
Unrealized gain (loss) on available-for-sale securities	508	(1,028)	332	(1,028)
Comprehensive (loss) income	$(2,393,549)	$(5,188,559)	$(9,131,687)	$80,392,466

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statement of Stockholders' Equity

(unaudited)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Compre-hensive	Non-controlling	Total Stockholders'
	Shares	**Amount**	**Capital**	**Deficit**	**Loss**	**Interest**	**Equity**
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
Issued stock to 401(k) plan	94,684	95	35,885	—	—	—	35,980
Stock compensation expense	—	—	217,147	—	—	—	217,147
Comprehensive loss:							
Net loss	—	—	—	(9,131,994)	—	(25)	(9,132,019)
Unrealized gain on available-for-sale securities	—	—	—	—	332	—	332
Total comprehensive loss	—	—	—	—	—	—	(9,131,687)
Balance, June 30, 2018	163,620,090	$163,620	$331,697,603	$(329,740,962)	$ (2,064)	$668,675	$2,786,872

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended	
	June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net (loss) income	$(9,132,019)	$80,393,494
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	75,498	161,751
Loss on disposal and abandonment of assets	—	806,710
Compounded interest on long term debt	84,576	182,680
Stock compensation expense	217,147	256,384
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	12,573,372	(14,642,466)
Inventory	—	1,470,826
Prepaid expenses and other assets	371,538	197,025
Accounts payable	(401,323)	(5,502,541)
Accrued and other liabilities	(112,274)	(3,948,055)
Deferred revenue	(5,037)	(2,315,037)
Net cash provided by operating activities	8,289,794	61,992,252
Cash flows from investing activities:		
Purchases of available-for-sale securities	—	(2,000,000)
Proceeds from sales of available-for-sale securities	200,000	—
Maturities of available-for-sale securities	800,000	—
Purchases of equipment	(3,165)	(8,170)
Net cash provided by (used in) investing activities	996,835	(2,008,170)
Cash flows from financing activities:		
Proceeds from issuance of common stock	200	54,319
Payment of debt-related costs	(7,153,000)	(1,314,102)
Principal payments on notes payable	(237,862)	(59,630,775)
Net cash used in financing activities	(7,390,662)	(60,890,558)
Net increase (decrease) in cash, cash equivalents and restricted cash	1,895,967	(906,476)
Cash, cash equivalents and restricted cash, beginning of period	2,795,006	6,540,578
Cash, cash equivalents and restricted cash, end of period	$4,690,973	$5,634,102

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 June 30, 2018 and for the three-month and six-month periods ended June 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 June 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.

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.

On March 3, 2017, pursuant to an Asset Purchase Agreement dated November 23, 2016 (the "Purchase Agreement"), the Company completed its previously announced sale to Cardinal Health 414, LLC ("Cardinal Health 414") of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the "Business"), including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration ("FDA") and similar indications approved by the FDA in the future (the "Product"), in Canada, Mexico and the United States (the "Territory") (giving effect to 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").

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).

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

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

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

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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 5.

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 June 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 June 30, 2018 and December 31, 2017 primarily consisted of the face amount of the notes less unamortized discounts. At June 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 June 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 June 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 six-month period ended June 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. **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. See Note 4.

d. **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. ASU 2014-09 allows a choice of transition methods: (a) a full retrospective adoption in which the standard is applied to all of the periods presented, or (b) a modified retrospective adoption in which the standard is applied only to the most current period presented in the financial statements with a cumulative-effect adjustment reflected in retained earnings. ASU 2014-09 also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity's nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those periods.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers – Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. ASU 2016-08 does not change the core principle of the guidance, rather it clarifies the implementation guidance on principal versus agent considerations. ASU 2016-08 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-08 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers – Identifying Performance Obligations and Licensing*. ASU 2016-10 does not change the core principle of the guidance, rather it clarifies the identification of performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. ASU 2016-10 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-10 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers – Narrow-Scope Improvements and Practical Expedients*. ASU 2016-12 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. ASU 2016-12 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year.

In December 2016, the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*. ASU 2016-20 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including loan guarantee fees, contract cost impairment testing, provisions for losses on construction- and production-type contracts, clarification of the scope of Topic 606, disclosure of remaining and prior-period performance obligations, contract modification, contract asset presentation, refund liability, advertising costs, fixed-odds wagering contracts in the casino industry, and cost capitalization for advisors to private and public funds. ASU 2016-20 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year.

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 in 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 three-month period ended March 31, 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.

e. **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 third quarter of 2018. We expect the adoption of ASU 2016-02 to result in an increase in right-of-use assets and lease liabilities on our consolidated statement of financial position 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 2015-09 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.

2. Liquidity

As disclosed in the Company's Annual Report on Form 10-K and other filings, the Company has been engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG") in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement, in the District Court of Harris County, Texas (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. Navidea's brief on the merits in this appeal is due on August 10, 2018, but this deadline is subject to potential extension. Navidea does not expect a ruling on this appeal until 2019 at the earliest.

On April 2, 2018, the Company entered into an Amendment to the Asset Purchase Agreement (the "Amendment"). 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.

On April 12, 2018 Navidea filed suit in the Court of Common Pleas for Franklin County, Ohio (the "Ohio Court") against CRG and certain of its affiliates (collectively, 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. CRG's motion to dismiss has been fully briefed and a decision on the motion is expected from the Court in the near future.

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. This motion to dismiss will be heard by the Texas Court on August 20, 2018.

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.

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

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to Platinum Partners 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. The Company was informed by PPVA that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately $1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid any amounts to PPVA or Dr. Goldberg given the pending dispute.

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 are 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 and the motion has been fully briefed with a decision expected from the Court in the near future.

The Company has experienced recurring net losses and recent unfavorable court rulings, and has used significant cash to fund its operations, all of which are factors that raise substantial doubt about our ability to continue as a going concern. 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 as the Company works to reduce spending. 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, the Company completed the sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer, including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the FDA and similar indications approved by the FDA in the future, in Canada, Mexico and the United States. In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately $80.6 million after adjustments based on inventory being transferred and an advance of $3.0 million of guaranteed earnout payments as part of the CRG settlement, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product.

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 $86.7 million for the six months ended June 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 $6.5 million in estimated taxes.

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

	June 30,	**December 31,**

	2018	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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Lymphoseek sales revenue	$—	$9,663	$—	$2,926,876
Cost of goods sold	—	24,216	—	388,408
Gross profit	—	(14,553)	—	2,538,468
Operating expenses:				
Research and development	2,453	75,196	2,453	358,729
Selling, general and administrative	—	—	—	820,203
Total operating expenses	2,453	75,196	2,453	1,178,932
(Loss) income from discontinued operations	(2,453)	(89,749)	(2,453)	1,359,536
Interest expense	—	—	—	(1,718,506)
Loss before income taxes	(2,453)	(89,749)	(2,453)	(358,970)
Benefit from income taxes	515	7,373	515	20,733
Loss from discontinued operations	$(1,938)	$(82,376)	$(1,938)	$(338,237)

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 six-month periods ended June 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 six-month periods ended June 30, 2018, the Company recognized revenue from contracts with customers of approximately $264,000 and 265,000, 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 six-month periods ended June 30, 2018.

Three Months Ended June 30, 2018	**Diagnostics**	**Therapeutics**	**Total**
Tc99m tilmanocept royalty revenue:			
Europe	$ 6,665	$ —	$6,665
India	—	—	—
China	—	—	—
Total	$ 6,665	$ —	$6,665
License revenue:			
NAV4694 sublicense	$ 257,709	$ —	$257,709
Other revenue:			
Additional stability studies	$ —	$ —	$—

Six Months Ended June 30, 2018	**Diagnostics**	**Therapeutics**	**Total**
Tc99m tilmanocept royalty revenue:			
Europe	$ 7,460	$ —	$7,460
India	—	—	—
China	—	—	—
Total	$ 7,460	$ —	$7,460
License revenue:			
NAV4694 sublicense	$ 257,709	$ —	$257,709
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 six-month periods ended June 30, 2018 and 2017:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017