NAVIDEA BIOPHARMACEUTICALS, INC.

Form 10-Q November 09, 2016

**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, 2016

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

For the transition period from to to

Commission File Number: 001-35076

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 31-1080091 (State or other jurisdiction of (IRS Employer

incorporation or organization) Identification No.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio 43017-7550 (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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company

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: 155,762,729 shares of common stock, par value \$.001 per share (as of the close of business on November 1, 2016).

# NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

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#### PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

	September 30,	December 31,				
	2016	2015				
ASSETS	(unaudited)					
Current assets:	· ·					
Cash	\$810,425	\$7,166,260				
Restricted cash	3,501,247	_				
Accounts and other receivables	3,474,329	3,703,186				
Inventory, net	804,882	652,906				
Prepaid expenses and other	839,978	1,054,822				
Total current assets	9,430,861	12,577,174				
Property and equipment	3,584,628	3,871,035				
Less accumulated depreciation and amortization	2,210,554	1,943,427				
	1,374,074	1,927,608				
Patents and trademarks	222,590	233,596				
Less accumulated amortization	41,604	47,438				
	180,986	186,158				
Other assets	203,679	273,573				
Total assets	\$11,189,600	\$14,964,513				
LIABILITIES AND STOCKHOLDERS' DEFICIT						
Current liabilities:						
Accounts payable	\$4,894,800	\$1,767,523				
Accrued liabilities and other	7,201,793	3,038,713				
Deferred revenue, current	15,037	1,044,281				
Notes payable, current	51,652,209	333,333				
Total current liabilities	63,763,839	6,183,850				
Deferred revenue	26,061	192,728				
Notes payable, net of discounts of \$0 and \$2,033,506, respectively	10,549,405	60,746,002				
Other liabilities	624,896	1,677,633				
Total liabilities	74,964,201	68,800,213				
Commitments and contingencies						
Stockholders' deficit:						
Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued						
or outstanding at September 30, 2016 and December 31, 2015, respectively	_	_				

Common stock; \$.001 par value; 300,000,000 shares authorized, 155,751,316

issued and outstanding at September 30, 2016; 200,000,000 shares authorized,

155,649,665 shares issued and outstanding at December 31, 2015, respectively	155,751	155,650
Additional paid-in capital	326,573,833	326,085,743
Accumulated deficit	(390,973,227)	(380,546,651)
Total Navidea stockholders' deficit	(64,243,643)	(54,305,258)
Noncontrolling interest	469,042	469,558
Total stockholders' deficit	(63,774,601)	(53,835,700)
Total liabilities and stockholders' deficit	\$11,189,600	\$14,964,513

See accompanying notes to consolidated financial statements (unaudited).

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Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

(unaudited)

	Three Months Ended				Nine Months Ended		
	September 30,				September 30,		
	2016	20	15		2016	2015	
Revenue:							
Lymphoseek sales revenue	\$6,690,090	\$2	,952,522		\$14,704,489	\$6,75	1,492
Lymphoseek license revenue	1,295,625	5	50,000		1,795,625	883,	333
Grant and other revenue	511,359	4	76,755		2,113,995	1,32	0,816
Total revenue	8,497,074	3	,979,277		18,614,109	8,95	5,641
Cost of goods sold	921,817	4	57,590		2,017,486	1,23	9,377
Gross profit	7,575,257	3	,521,687		16,596,623	7,71	5,264
Operating expenses:							
Research and development	1,276,053	3	,902,155		6,461,154	10,1	30,517
Selling, general and administrative	2,940,773	3	,942,609		9,925,574	13,4	85,576
Total operating expenses	4,216,826	7	,844,764		16,386,728	23,6	56,093
Income (loss) from operations	3,358,431	(4	4,323,077	)	209,895	(15,9)	949,829)
Other income (expense):							
Interest expense, net	(2,566,171	) (2	2,148,369	)	(12,288,169)	(4,69)	00,686 )
Equity in loss of R-NAV, LLC	_	(2	26,785	)	(15,159)	(295	,217 )
Loss on disposal of investment in R-NAV, LLC	_	_			(39,732)	_	
Change in fair value of financial instruments	(839,298	) (	1,577,275	)	1,755,989	(1,70	02,902 )
Loss on extinguishment of debt		_			_	(2,44)	0,714
Other, net	(12,498	) 4	,402		(49,916)	26,1	00
Total other expense, net	(3,417,967	) (.	3,748,027	)	(10,636,987)	(9,10	03,419
Net loss	(59,536	) (	8,071,104	)	(10,427,092)	(25,0	053,248)
Less loss attributable to noncontrolling interest	(159	) (.	340	)	(516)	(681	)
Deemed dividend on beneficial conversion feature of							
MT Preferred Stock	_	_	_		_	(46,0	)000
Net loss attributable to common stockholders	\$(59,377	) \$(	8,070,764	)	\$(10,426,576)	\$(25,0	98,567)
Loss per common share (basic and diluted)	\$(0.00	) \$(	0.05	)	\$(0.07)	\$(0.17	)
Weighted average shares outstanding (basic and							
diluted)	155,481,278	8 1	50,186,131	1	155,390,911	150,	030,638

See accompanying notes to consolidated financial statements (unaudited).

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statement of Stockholders' Deficit

(unaudited)

				Additional			Total
	Prefer		1_	D.11 L.	A 1-4- 1	NI	: .C41.1 - 1.1!
	Stock Shares	Common Stoc mou <b>Sh</b> ares	K Amount	Paid-In Capital	Accumulated Deficit	Interest	ingtockholders' Deficit
Balance,				1			
December 31,							
2015	—\$	— 155,649,665	\$155,650	\$326,085,743	\$(380,546,651)	\$ 469,558	\$(53,835,700)
Issued restricted							
stock	_	— 168,000	168	_	_	_	168
Canceled forfeited							
restricted stock	_	<b>—</b> (206,000 )	(206)	178	_	<del>_</del>	(28)
Issued stock in							
payment of							
Board retainers		<b>—</b> 72,649	72	56,537			56,609
Issued stock to							
401(k) plan		<b>—</b> 67,002	67	120,733	_	_	120,800
Stock							
compensation							
expense	_			310,642			310,642
Net loss	_		_	_	(10,426,576)	(516)	(10,427,092)
Balance,					,	· · · · · ·	·
September 30,							
2016	—\$	— 155,751,316	\$155,751	\$326,573,833	\$(390,973,227)	\$ 469,042	\$(63,774,601)

See accompanying notes to consolidated financial statements (unaudited).

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Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

Nine Months Ended

September 30,

2016 2015

Cash flows from operating activities:

Net loss \$(10,427,092) \$(25,053,248)

Adjustments to reconcile net loss to net cash used in operating activities: