UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported)	August 16, 2018

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35076	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4995 Bradenton Avenue, Suite 240, Dublin, Ohio	43017
(Address of principal executive offices)	(Zip Code)

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

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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. ☐

Item 8.01. Other Events.

On August 16, 2018, Navidea Biopharmaceuticals, Inc. ("*Navidea*") issued a press release announcing certain business updates. Navidea also announced that it intends to make a presentation relating to such business updates, among other things, at its 2018 Annual Meeting of Stockholders, to be held on the date hereof.

A copy of the press release is attached hereto as Exhibit 99.1 and a copy of the materials Navidea intends to use in the presentation is attached hereto as Exhibit 99.2. Each of Exhibit 99.1 and Exhibit 99.2 are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release issued by Navidea Biopharmaceuticals, Inc., dated August 16, 2018.
99.2	Investor presentation, dated August 16, 2018.

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 hereunto duly authorized.

Navidea Biopharmaceuticals, Inc.

Date: August 16, 2018

By:/s/ Jed A. Latkin
Jed A. Latkin
Interim Chief Executive Officer, Chief
Operating Officer, and Chief Financial Officer

Exhibit 99.1

NAVIDEA BIOPHARMACEUTICALS ANNOUNCES DETAILS OF 2018 ANNUAL GENERAL MEETING

Michael Goldberg, M.D. Resigns as Chief Executive Officer and Director of Navidea

Jed A. Latkin, Chief Financial Officer and Chief Operating Officer, Appointed Interim Chief Executive Officer and Director

Conference call to take place August 16th, 2018 at 5:00pm EDT

DUBLIN, Ohio–As previously announced, Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) ("Navidea" or the "Company"), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, will host a conference call today, August 16, 2018, at 5:00pm EDT to discuss details of the Annual Meeting for its shareholders, to be held today in Fort Lee, New Jersey under the chairmanship of Michael Rice, director of Navidea.

During the meeting, management will provide updates on the following:

- The Rheumatoid Arthritis and Activated Macrophage Data has been submitted to the U.S. Food and Drug Administration ("FDA"); a meeting with the FDA is now confirmed for late September.
- The terms of Dr. Goldberg's separation from Navidea.
- The leadership transition plan, including Mr. Jed A. Latkin's new role as Interim Chief Executive Officer and member of the board, effective August 14, 2018.
- The business plan moving forward for Navidea's subsidiary, Macrophage Therapeutics, Inc. ("MT"), which will now be led by Dr. Goldberg.

Going forward, Dr. Goldberg will serve as Chief Executive Officer of MT and will concentrate all of his attention and efforts on progressing the developments taking place. In this role, Dr. Goldberg will focus on addressing MT's long-term funding needs as well as progressing its clinical pipeline.

"Navidea is grateful to Dr. Goldberg for his extensive contributions to the Company over the last 5 years, helping to build its leadership position in precision medicine," said Mr. Jed A. Latkin, Interim Chief Executive Officer. "We believe this business transition will allow Navidea and our subsidiary, Macrophage Therapeutics, to focus their efforts on advancing the novel pipelines and delivering on our mission. Our goal throughout these corporate changes is to consistently create long-term value for our stakeholders as we shift the focus of the business and strive towards improving patient care. Furthermore, we are extremely excited that the FDA has granted us a meeting request in late September. We look forward to advancing our second product to commercialization."

Jed Latkin has served as Navidea's Chief Financial Officer and Chief Operating Offer since 2016. Previously, he was a Portfolio Manager at Nagel Avenue Capital from 2010 to 2016, at ING Investment Management from 2006 to 2010, and at Morgan Stanley from 2002 to 2006.

Conference Call Details

Investors and the public are invited to access the live audio webcast through the link below. Participants who would like to ask questions during the question and answer session must participate by telephone. Participants are encouraged to log-in and/or dial-in fifteen minutes before the conference call begins.

Event:	Annual Meeting Discussion and Update on Current Corporate Events and Outlook
Date:	Thursday, August 16, 2018
Time:	5:00 pm (Eastern Time)
U.S. & Canada Dial-in:	877-407-0312
Conference ID:	13682395
Webcast	https://webcasts.eqs.com/navidea20180816

The presentations to shareholdersat the Annual Meeting as well as the Webcast of the Annual Meeting Discussion and Update on Current Corporate Events and Outlook Conference call will be posted on August 16, 2018 on the corporate website.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) is a biopharmaceutical company focused on the development of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on its Manocept™ platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making, and targeted treatment. Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc 99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. The development activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through global partnering and commercialization efforts.

For more information, please visit www.navidea.com.

Forward-Looking Statements

This release and any oral statements made with respect to the information contained in this release 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. 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: the timing of, and our ability to, move forward with our business plans, including as they relate to Macrophage Therapeutics, Inc., general economic and business conditions, both nationally and in our markets; our history of losses and uncertainty of future profitability; the final outcome of the CRG litigation in Texas; our ability to successfully complete research and further development of our drug candidates; the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates; our ability to successfully commercialize our drug candidates; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; and other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other SEC filings. You are urged to carefully review and consider the disclosures found in our SEC filings, which are available at www.sec.gov or at http://ir.navidea.com.

Investors are urged to consider statements that include the words "will," "may," "could," "should," "plan," "continue," "designed," "goal," "forecast," "future," "believe," "intend," "expect," "anticipate," "estimate," "project," and similar expressions, as well as the negatives of those words or other comparable words, to be uncertain forward-looking statements.

You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be incorrect. 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.

Contacts

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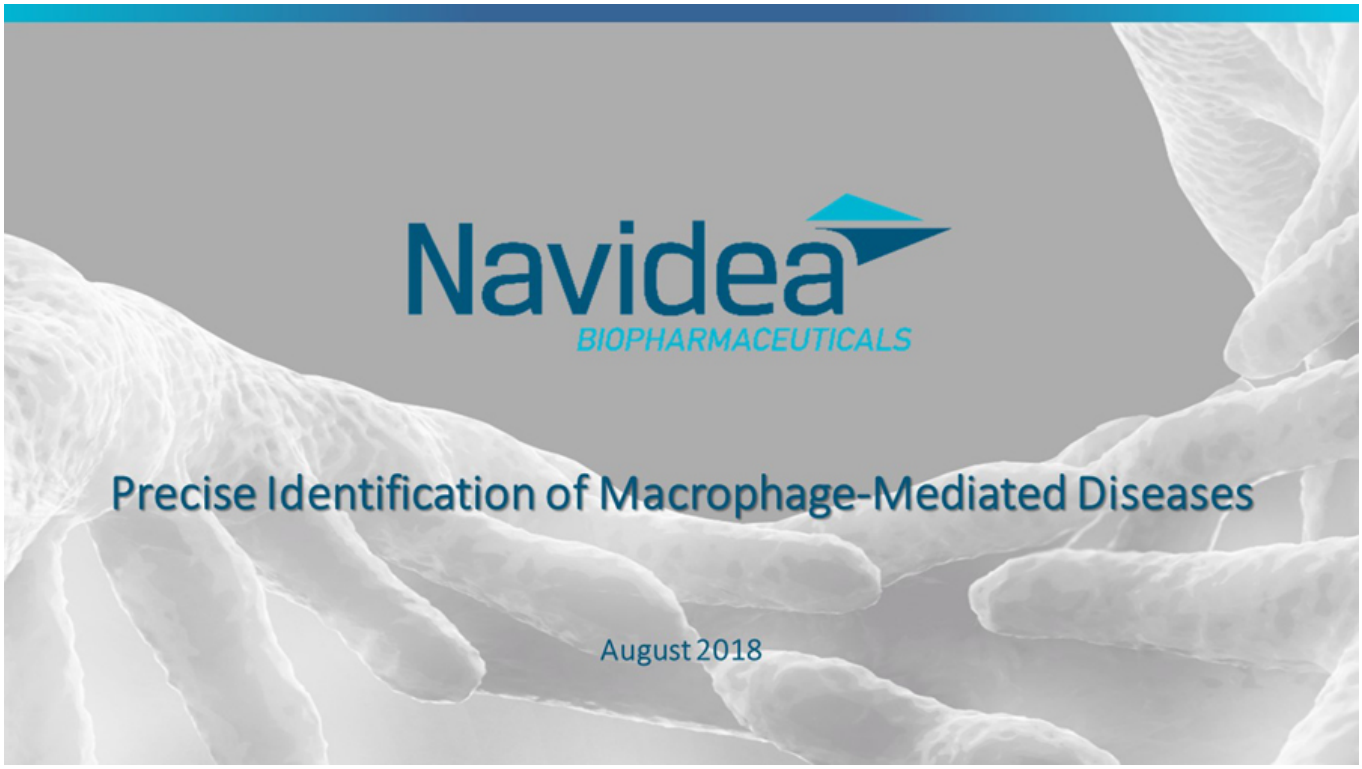
jlatkin@navidea.com

or

Edison Advisors
Joseph Green, 646-653-7030
jgreen@edisongroup.com

Source: Navidea Biopharmaceuticals, Inc.

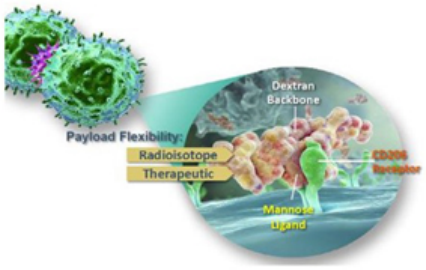
Exhibit 99.2


Navidea
BIOPHARMACEUTICALS
Precise Identification of Macrophage-Mediated Diseases
August 2018

Disclaimer

The private securities litigation reform act of 1995 (the act) provides a safe harbor for forward-looking statements made by or on behalf of the company. Statements in this presentation, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. You are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. You are further cautioned that the foregoing list of important factors is not exclusive. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Our Technology



Target CD206 Activated Macrophage receptor

Our proprietary activated macrophage targeting system is capable of identifying and measuring macrophage activity in-vivo

Navidea is marketing its Biomarker technology for use as a novel drug development tool in ongoing and future Oncology

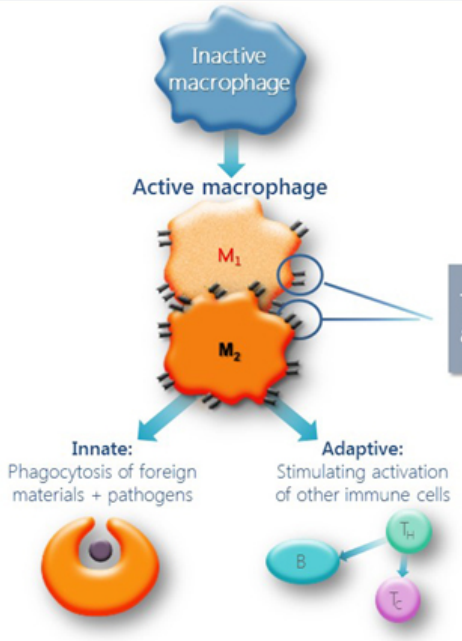
Tilmanocept combines:

- Mannose ligand for binding CD206 receptors on activated macrophages → ✓ **Seek**
- Radioisotope → ✓ **Identify**

Macrophages and CD206 Receptors

Only Activated Macrophages express CD206

Navidea BIOPHARMACEUTICALS



Macrophages are activated in multiple ways

Environmental Exposure
- Viruses
- Other infectious agents
- Drugs/chemicals
- Other (e.g. ultraviolet light)

Hormonal Effects
- Intrinsic and extrinsic
- Variable depending on disease

The mannose receptor, CD206, is only expressed on activated macrophages and dendritic cells (CD209)

Activated macrophages function in both innate + adaptive immunity

The Role of Macrophages in Human Biology

Navidea BIOPHARMACEUTICALS

- Macrophages are immune system cells that respond to tissue damage or infection
- Activated macrophages are stimulated by cytokines or bacteria to respond to invading or infected cells:
  - Help clear infectious agents, repair damaged tissue
  - Alter microenvironment to suppress or promote disease-causing cells
  - **Have unique receptors that enable cellular targeting**

Restructuring Relationship with Macrophage Therapeutics

Unlocking and enabling value creation at "NAVB" via the therapeutics franchise

Spinout Rationale

- Current structure severely hampers the ability to finance Macrophage Tx through traditional Venture Capital structure
- Minimal overlap between Diagnostic and Therapeutic focused institutional investors
- Macrophage Tx capital needs are significant relative to Navidea
- Minimize NAVB dilution to fund Therapeutic development

Post Spinout Structure

- Navidea will maintain a passive ownership stake in Macrophage Tx
  - Depending on NAVB'S own financial needs MT shares will either be kept for access to capital to fund NAVB or distributed to shareholders at some future date
  - In any event progress at MT will translate to improved valuation in NAVB
- Macrophage Therapeutics BoD and potential institutional investors will hold controlling vote
  - Structure that mirrors typical Venture Capital investment

The Navidea Opportunity Post MT Spinout

Near term commercial opportunities and Macrophage valuation milestones

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Biomarker 	✓Ongoing discussion to utilize Tilmanocept in planned clinical trials
	✓Does not require additional approvals or reimbursement to generate revenue
	✓Applications: Cardiovascular, Cancer, RA, NASH,vand Neuroinflammatory disease
Clinical Diagnostics 	✓Rheumatoid Arthritis (Planned Ph3 Trial in 4Q18/1Q19)
	✓NASH Diagnostic to replace Biopsy (Planned completion 4Q18)
	✓Cardiovascular imaging (Ongoing Ph2)
	✓Neuroinflammatory Diseases (generating proof of concept data)
Macrophage Tx 	✓Creating value at NAVB via passive stake in Macrophage Therapeutics
	✓Pursuing Orphan Disease with abbreviated regulatory pathway
	✓Multiple valuation milestones over the next 2 quarters
	Pursuing external partners and investors

Our Biomarker Approach

Biomarker: Overview

Near term commercial opportunity that obviates additional regulatory clearance

Three Key Attributes of our Biomarker Approach

- (1) Clear unmet need to reduce clinical trial cost burden
- (2) No additional regulatory requirements to generate commercial revenue
- (3) Potential revenue opportunity for NAVB is significant

Biomarker addresses unmet need

Current Clinical Landscape & Monitoring Market Opportunity

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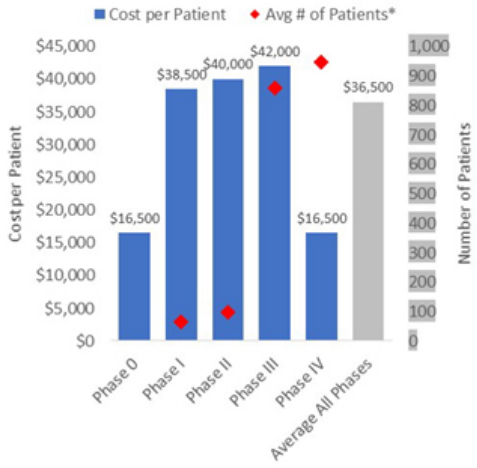
- Improvement in Savings for Clinical Trial Costs and Preventative Screening
  - *Average cost per patient in clinical trials today: $36,500*
  - *Site monitoring, recruitment and retention account for approximately one-third of trial costs*
- *Focused recruitment and patient screening to optimize trial outcomes and minimize SAE's and reduce overall patient mortality*
  - *Ongoing patient monitoring and dose optimization*
  - *End of trial scanning for outcomes*
  - *Cut overall spend and time to market*



- *Patient enrollment numbers reflect oncology trials*
- *Source: ClinicalTrials.gov*

Biomarker limits regulatory hurdles

Selling into clinical trials obviates need to obtain additional regulatory clearances

- Regulations permit selling Tilmanocept to Biopharmas & CROs for use in registered clinical trials
  - US and Europe (Japanese approval expected in the future)
- Potential CRO partners have cited FDA approval and superb safety profile as key selling points
- Data generated through biomarker approach will help accelerate regulatory pathway for future clinical diagnostics

Biomarker revenue opportunity is robust

Potential to integrate Tilmanocept into thousands of clinical trials

Navidea BIOPHARMACEUTICALS

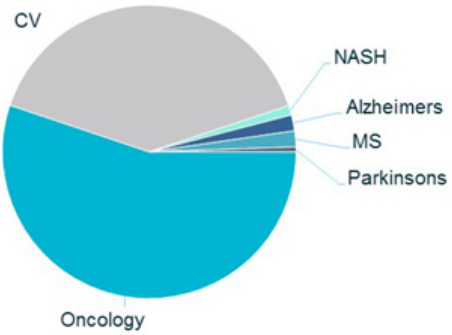
>500,000
Patients currently being recruited for FDA registered clinical trials in applicable disease areas

×

$5,000/dose
NAVB sales price

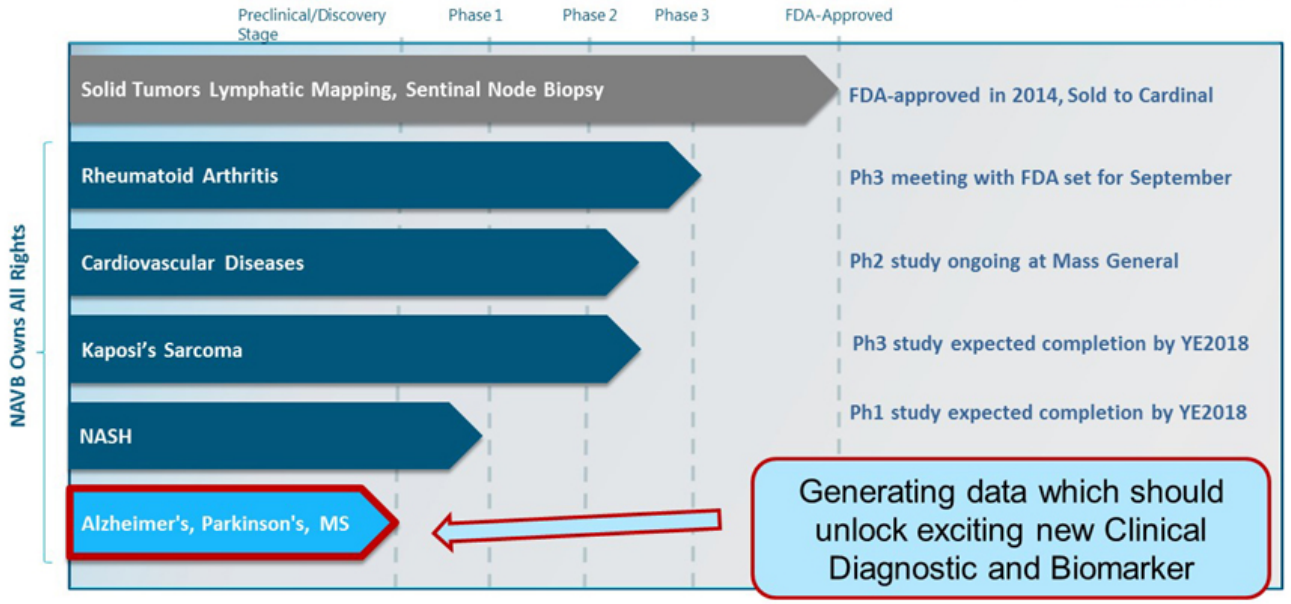
=

$2.5B
Potential revenue for research purposes *only*



Our Clinical Diagnostics Strategy

Navidea Product Pipeline



Our Pipeline: What's New?

Navidea BIOPHARMACEUTICALS

Detection & Monitoring of Neuroinflammatory Diseases

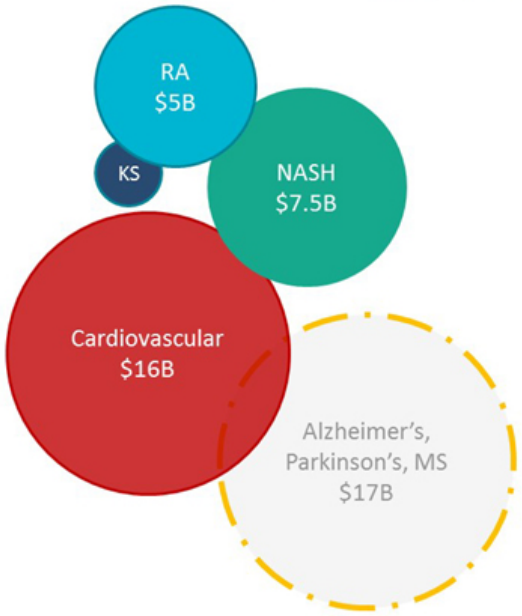
- Anticipate data indicating use of Tilmanocept as a Neuroinflammation diagnostic imminently
  - **Initial data readout expected over next several weeks**
    - Applications in Alzheimer's, Parkinson's, Multiple Sclerosis
    - Detection & Monitoring
- Clear unmet medical need for an early detection tool and biomarker for drug development
  - Ph2 results of Biogen's BAN2401 highlight clear need for diagnostic and biomarker tool for Alzheimer's drug development

Brain Perivascular Macrophages Initiate the Neurovascular Dysfunction of Alzheimer Aβ Peptides. Circ Res. 2017 Jul 21;121(3):258-269. doi: 10.1161/CIRCRESAHA.117.311054. Epub 2017 May 17.

Sizeable addressable markets

Pipeline addresses unmet preventative screening needs

- Rheumatoid Arthritis FDA approval will pave the way for additional FDA approved clinical Diagnostics
- Will pursue both **diagnostic** and **screening** pathways for Cardiovascular disease
- Commercialization strategy will vary by indication



Corporate Overview

Targeting Activated Macrophages to Detect, Monitor and Treat Disease

Navidea BIOPHARMACEUTICALS

Building off FDA/EMA-approved diagnostic product
Leveraging FDA approved Lymphoseek® to expand to more attractive clinical diagnostic end markets

Technology platform applicable to multiple disease states
RA, CV, NASH, Cancer and Neuroinflammatory Diseases

Targeting CD206 receptors on activated macrophages
Enables higher affinity and more precise non-invasive imaging

Business Strategy
Leveraging proprietary technology to create and maximize shareholder value through new products, collaborations, entities, and partnerships

Navidea Imaging Strategy

Image M1 or M2 Mediated Disease

Dose it

Same for all indications

3 hour image RA

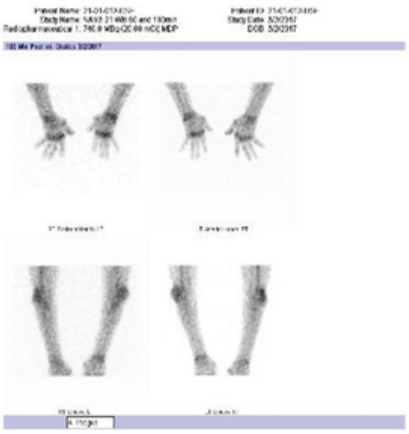
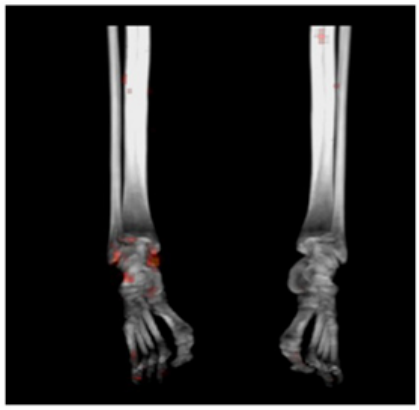


Image it

Focus the camera on area of interest

High Resolution Imaging



Cardiovascular Disease

Potential diagnostic and screening opportunity with large addressable market

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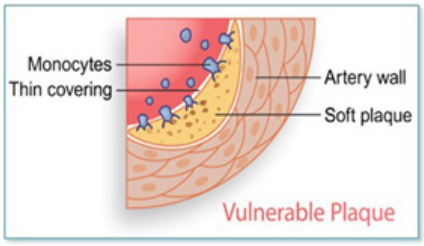
Detect High-risk Plaque

- Fat droplets in arteries induce cytokine release
- Cytokines recruit monocytes, which convert to macrophages
- Activated macrophages are potential markers of cardiovascular disease



NIH Grant with MASSACHUSETTS GENERAL HOSPITAL

- **Phase I study completed under existing IND evaluating imaging and detection of vulnerable plaque**
  - Published J Infection Diseases 16 Jan 2017: Application of a Novel CD206+ Macrophage-Specific Arterial Imaging Strategy in HIV Application of a Novel CD206
- **Additional Phase 2 study underway**

Quantifiable Inflammation Score

Computer Read of CV images Creates Quantitative Inflammation Score

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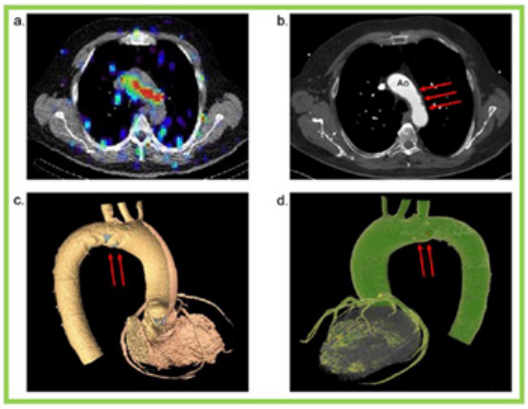
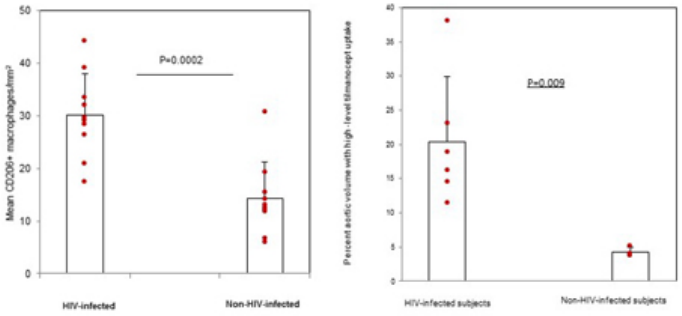
Compiled 2D/3D Imaging



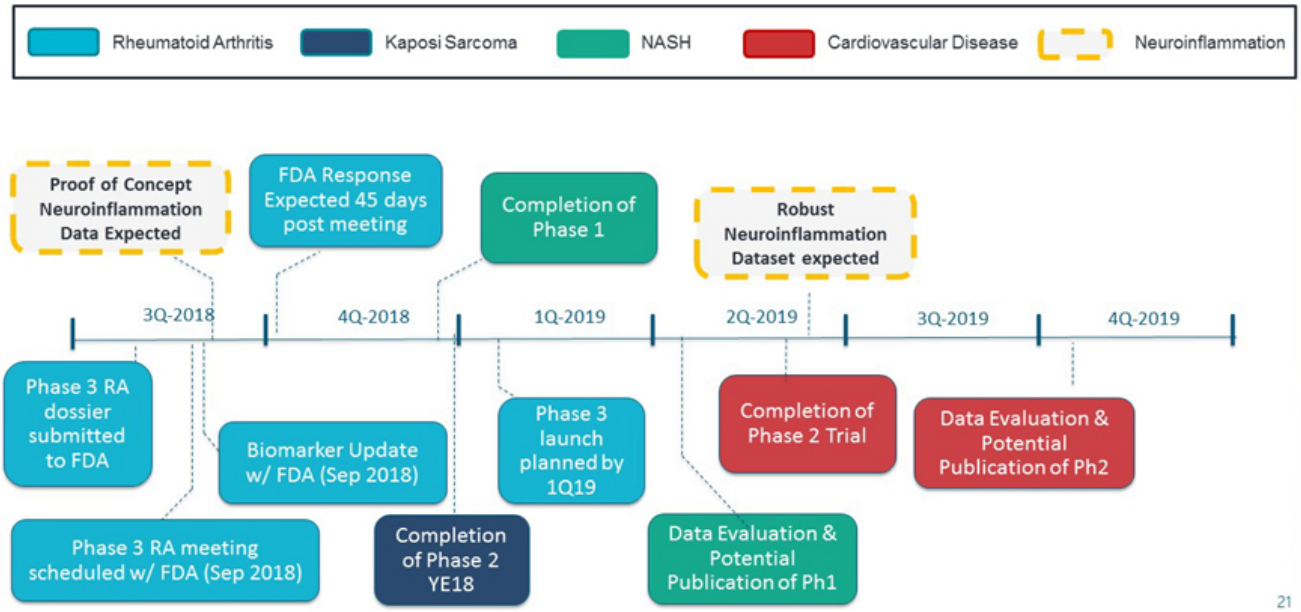
Computer Generated Score of CV Images



Clinical Diagnostics Catalyst Calendar

Clinical Diagnostics Catalyst Calendar

Navidea BIOPHARMACEUTICALS



Restructuring Relationship with Macrophage Therapeutics

Pathway to Create Value for “NAVB”

Therapeutic Concept

Selectively targeting Activated Macrophages

Navidea BIOPHARMACEUTICALS

Platform for immuno-constructs that preferentially target CD206+ (and CD209+ dendritic cells) activated macrophages

1 GPS	2 Delivery	3 Payload
		
Mannose Moiety With One Hardwired Address - CD206 Activated Macrophages	Manocept™ Backbone	▪ Chemotherapeutics ▪ Immune-modulators ▪ Tc^{99} ▪ Other Isotopes

Preclinical Models Validate Macrophage Strategy

Navidea BIOPHARMACEUTICALS

Arthritis

- Results report clear statistically significant anti-inflammatory activity with no apparent significant clinical signs relating to off target effects.

Asthma

- Results show a decrease in all three pro-inflammatory markers evaluated that are secreted by disease causing macrophages that successfully demonstrates an anti-inflammatory effect. Study repeated by large pharma collaborator with comparable results with different mix of pro-inflammatory markers.

NASH

- Results demonstrate statistically significant reduction in NASH related inflammation
- No evidence of damage to resident liver macrophages called Kupffer cells or other liver damage
- Three doses of MT1002 tested in NAFLD-NASH model and 1 dose of MT 2002 and MT 1002 tested in NASH fibrosis model

Neuro-inflammation

- Krabbe Disease: Data from the definitive naturally occurring animal model the Twitcher mouse.
  1. Evidence that we can normalize morphology of macrophage by converting from M1 to M2
  2. Enabled normal weight gain
  3. Significantly reduced or eliminated disease progression for time period evaluated so far
  4. Awaiting pathology data on brains to confirm protective effect and BBB permeability.

Cancer

- Results showed an immediate effect on the rate of tumor growth and in the slower growing tumor the inhibition in tumor growth rate remained throughout the duration of the study
- Synergy demonstrated with addition of a targeted antibody resulting in the ability to reduce the dose of the companion antibody
- This offers the potential for lower side effects, reduced resistance and dramatically lower cost

MT-2000: An activated macrophage targeted steroid

- Designed to inhibit inflammation caused by overactive macrophages
- Converts pro-inflammatory M1 Macrophages to anti-inflammatory M2 Macrophages
- Receptor mediated delivery improves efficacy and eliminates off target toxicity

Restructuring relationship with Macrophage Therapeutics

Recently generated pre-clinical data points to accelerated FDA pathway

Why Now?

- Pre-clinical study just recently provided promising data in the treatment of **a rare orphan Neuroinflammatory Disease**
  - **MT has selected this approach for identifying its Lead Indication and Lead Candidate**
    - Provides an accelerated pathway to regulatory milestones and approval
    - Significantly limits capital needs to generate first-in-human data
  - MT has significant capital needs that must be addressed to bring any product to market
    - Current corporate structure limits MT's ability to raise capital
  - MT has hired leading regulatory consultants to pursue **Orphan Drug Designation** and potential **Pediatric Rare Disease Priority Review Voucher**

Rare Pediatric Disease Voucher

Potential source of non-dilutive capital for MT and NAVB

Rare Pediatric Disease Voucher

- Potential to provide both MT and Navidea with non-dilutive capital
- MT plans to submit Rare Pediatric Disease Qualification package to the FDA by YE2018
  - Have hired leading CRO

Last 5 Rare Pediatric Disease Vouchers have sold for >$100 mn

Company Awarded Voucher	Voucher Acquirer	Date Sold	Sale Price ($)
Spark Therapeutics	Jazz	Apr-18	$110 mn
Ultragenyx	Novartis	Dec-17	$130 mn
BioMarin	Undisclosed	Nov-17	$125 mn
Sarepta	Gilead	Feb-17	$125 mn
Asklepion Pharma (Retrophin)	Sanofi	May-15	$245 mn

Macrophage Tx Lead Indication

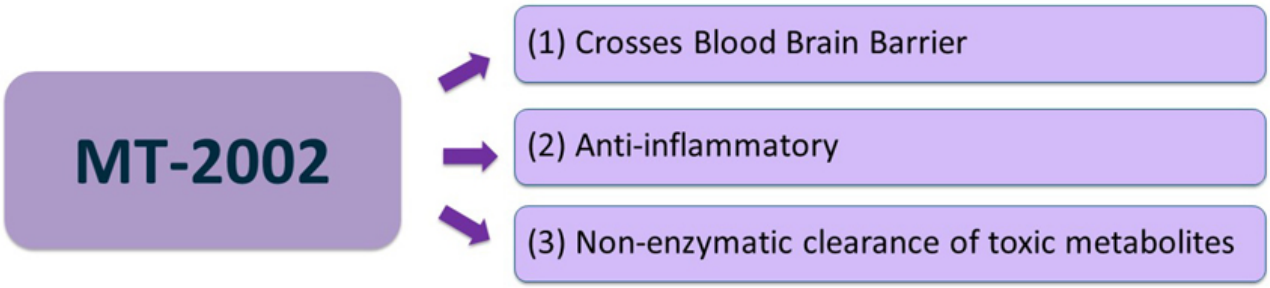
Rare pediatric orphan disease with unmet medical need

- Lysosomal storage disease resulting in myelin damaging neuro-inflammation
  - Disease diagnosed at 6 months old, typically fatal by 2-3 years
- MT is currently exploring the utility of MT-2000 class (anti-inflammatory)
  - We anticipate:
    - FDA Orphan Drug Designation (ODD)
    - Qualification of a Rare Pediatric Disease Priority Review Voucher
- Pending FDA ODD & Voucher qualification MT will pursue this indication first
  - **MT will explore follow-on neuro-inflammatory diseases**

Krabbe: Proof of Concept for Neuroinflammation

Krabbe Disease will prove three key therapeutic traits of MT-2002

Navidea BIOPHARMACEUTICALS



Proving these attributes will open the door to blockbuster neuroinflammatory indications…(and systemic inflammatory indications)

Krabbe: Proof of Concept for Neuroinflammation

Krabbe Disease will prove three key therapeutic traits of MT2000

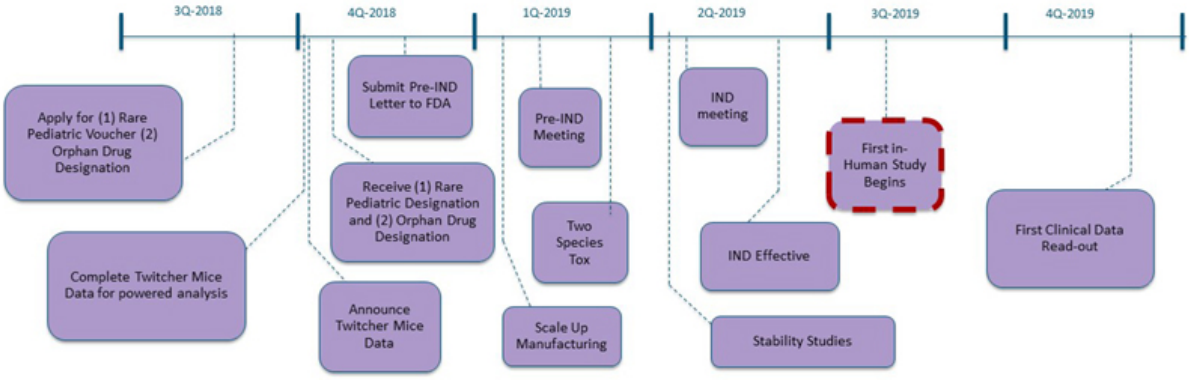
Macrophage Catalyst Calendar

Multiple opportunities to create value over the next 15 months

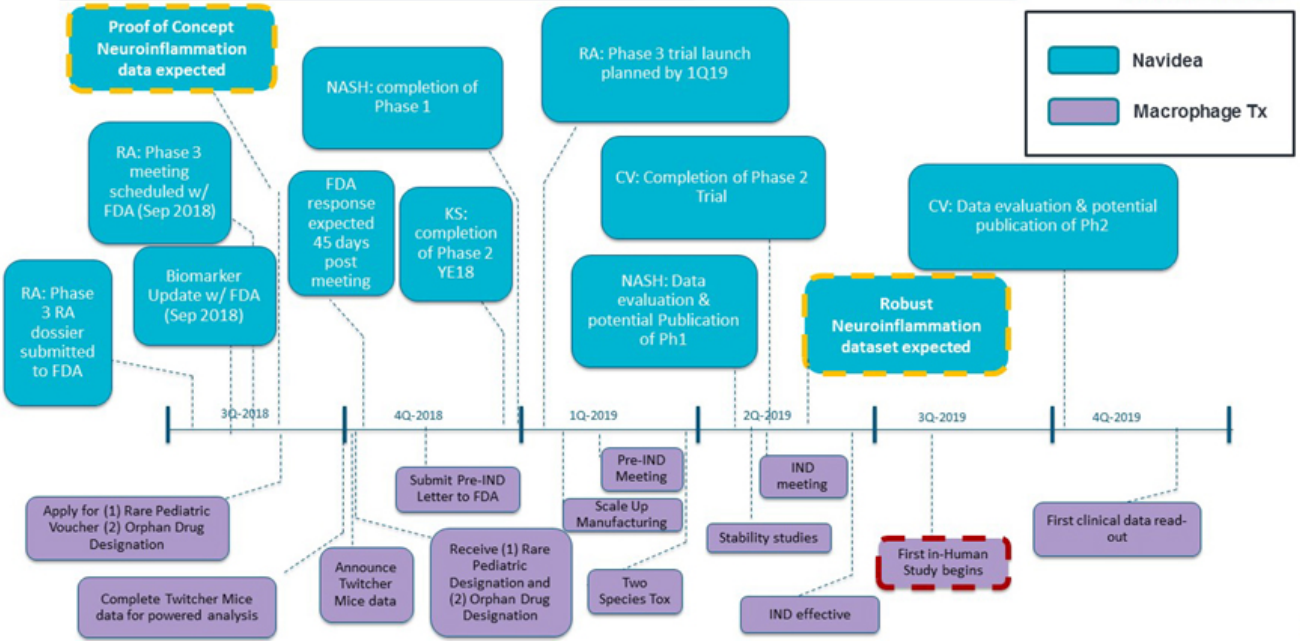
Navidea BIOPHARMACEUTICALS

Orphan indication provides accelerated regulatory pathway

- Provides numerous potential valuation catalysts to create value for Macrophage Therapeutics
- Value creation at Macrophage will directly translate to **value creation for "NAVB"**



Exciting next 15 months for Navidea and MT



End of Phase 2 Meeting with FDA

Timeline

Timeline

- July 11th – Meeting Request Sent to FDA
- August 9th – Briefing Book Sent to FDA (Includes questions)
- Late September – 90 Minute Meeting with FDA
- Will be utilizing KOLs for the meeting with the FDA
- Up to 45 days post-meeting – Receive meeting minutes with actions and agreements from FDA
- Q1 2019 – Commence Trial post FDA guidance

Thank you

Navidea
BIOPHARMACEUTICALS

Contact Details

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