

NAVIDEA BIOPHARMACEUTICALS, INC.

Form DEFA14A

July 20, 2018

SCHEDULE 14A INFORMATION

**Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934 (Amendment No.)**

XFiled by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement

Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

Definitive Proxy Statement

XDefinitive Additional Materials

Soliciting Material under §240.14a-12

NAVIDEA BIOPHARMACEUTICALS, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

XNo fee required.

Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3)

Edgar Filing: NAVIDEA BIOPHARMACEUTICALS, INC. - Form DEFA14A

Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

At 5:00 p.m. E.T. July 19, 2018, Navidea Biopharmaceuticals, Inc. ("*Navidea*") held a Question & Answer (Q&A) Session focused on Navidea's corporate progress as well as an update on the corporate proxy with Jed Latkin, Chief Financial and Operating Officer, and Michael M. Goldberg, M.D., President and Chief Executive Officer of Navidea (the "*Conference Call*"). A copy of the script used for the Conference Call appears below. A webcast of the Conference Call will be made available on the Investor Relations section of Navidea's website at www.navidea.com.

Navidea Biopharmaceuticals, Inc.

Question & Answer (Q&A) Session

July 19, 2018

Corporate and Proxy Update Call Script

Operator Remarks: Good Afternoon ladies and gentlemen, thank you for standing by. Welcome to Navidea Biopharmaceuticals' Corporate Update and Proxy Clarification call. During today's presentation all parties will be in a listen-only mode; following the presentation, the conference call will be opened to questions. If you have a question, please press star, then one, on your touchtone phone. If you would like to withdraw your question, please press the hash key. This conference is being recorded today, July 18, 2018. I'd like to turn the conference call over to Jed Latkin, Chief Financial and Operating Officer for Navidea Biopharmaceuticals, Inc. Please go ahead, sir.

Welcoming remarks and forward-looking statements – Jed Latkin: Thank you and welcome everyone to this afternoon's Corporate Update and Proxy CLARIFICATION call. Following our prepared remarks, we will open up the conference call to a question and answer session. Our call today will be led by our Chief Executive Officer, Dr. Michael Goldberg.

But, before we being our formal remarks, I would like to remind everyone that some of the statements on this conference call may be considered "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, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. Words such as "expects," "anticipates," "intends," "plans," "aims," "targets," "believes," "seeks," "estimates," "optimizing," "potential," "goal," "suggests" and similar expressions identify forward-looking statements. These forward-looking statements relate to the effectiveness of the Company's bodily-fluid-based diagnostic tests as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include the Company's failure to obtain necessary regulatory clearances or approvals to distribute and market future

products in the clinical IVD market; a failure by the marketplace to accept the products in the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company's intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; and other risks identified in the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about the Company's business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are made as of the date of this conference call, and, except as required by law, the Company does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

Prior to turning the call over to Dr. Goldberg management would like to clarify that this call is in no way meant to supplement or change the proxy in any way. Please refer to the proxy materials that have been sent to you and we encourage everyone to vote their shares. This call is intended to explain the materials that have been sent to you and to clarify the details that are contained within the packets that all shareholders of record have received. Our remarks as well as the question and answer session is not intended to influence shareholders vote in anyway.

I would now like to turn the call over to Dr. Michael Goldberg. Michael,

Dr. Goldberg: The purpose of this call is to discuss the requested items that are in front of the Navidea investors. Because of SEC rules we have an obligation to ask the shareholders for their approval of these items as they are impactful on the Company's ability to operate. Many investors have asked for further clarification on the proxy materials and this call is intended to do just that. We will not be changing or modifying anything in the proxy with this question and answer session.

We are a very small company with limited resources and we have quite a few highly engaged investors who are eager to weigh in on these issues and judging from the calls and postings of Navidea's investors we see there is a lot of confusion and that appropriately leads to concerns that need to be addressed. Once again I would like to reiterate, the purpose of this call is to address matters that have been brought to our attention and hopefully answer any questions investors may have.

It's very important to management that we be open and transparent at all times and address any outstanding concerns due to the items contained in the proxy. We want to address the questions asked and answered individually to shareholders in a forum open to all shareholders and archived for their review should they not be available to participate in this call live.

We will start by reviewing questions submitted in advance by shareholders with the focus on the issues specifically enumerated in the proxy. There are 4 items up for vote. We did not receive any questions or other feedback regarding the proposal to elect, Dr. Claudine Bruck as a director, so we won't address that in prepared remarks but of course are happy to answer specific questions when we go to the open Q&A. The same applies to the proposal to ratify the accountants for another 1 year term.

We will focus on the two proposals that appear to have engendered questions from investors. The first of these is a proposal to approve a potential amendment to our amended and restated certificate of incorporation to effect a reverse split of the Company's common stock, as determined by the Board of Directors at its discretion, of a ratio of not less than one-for-five and not more than one-for-twenty. If this proposal is approved, it will give the Board of Directors the OPTION (but not the obligation) to undertake a reverse split of the shares of the Company, and we will discuss why we are not simultaneously seeking to offset the reverse split with a pro rata decrease in the shares outstanding.

The second of the two proposals that generated investor feedback is the proposal to amend the Company's 2014 Stock Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under the plan by 10,000,000 shares. On this call, we will also discuss the reasons that we believe this is important.

Before I hand the call over to Jed Latkin, the company's COO and CFO to discuss the rationale in detail for the requested actions, I wanted to spend a few minutes providing some context that we believe will be helpful for our investors in making the decision on how to vote their shares. This brief overview traces the financing history of the company from its initial public offering to where we stand today. The purpose of this historical review is to provide

context as to why we believe we have had difficulty attracting institutional investor interest and to share our thoughts about why the reverse split is a tool among others that will help to changing this long standing issue. As we have said many times before a reverse split in and of itself is not a stand-alone solution to attracting investors to Navidea. It is a helpful tool if appropriately deployed. What is critical is the ability to demonstrate that the investment is worth the risk.

Navidea went public in November of 1992 at 6 dollars a share in a very small non-institutional investor IPO through GKN Securities. The Company issued 1.1 million shares and at the time had a total outstanding share count of approximately 8 million shares. The company was focused on developing a product called RIGGs and was in phase 2 at the time of the IPO. The Company issued shares for the MonoCarb acquisition in March of 1994 and then did a series of 3 small secondaries with such luminary investment banks as Sunrise Securities. RIGGS powered the company to its ONLY institutional underwritten financing in its history with Montgomery securities a leading biotech and technology underwriter in 1996. Montgomery, who had already started a relationship with the company in mid-1995 issued 1.75 million shares at \$18.50 a share. The financing that raised \$32.4 million was to complete phase 3 and launch the product. Post financing the company had 19.6 million shares outstanding and a market cap of \$362.6 million. In December 1998 after RIGGs failed its phase 3 trial and after Navidea spent an estimated \$100 million on its development, Navidea shelved the RIGGS program. One year later the company was trading below a dollar and had a market cap of \$21.3 million. The Company had a medical device called the Neoprobe and was generating some revenues thru its JNJ distribution partner. The company in-licensed Lymphoseek from UC San Diego and acquired another medical device company called Cardiosonix for a total of 11.8 million shares representing 32.3% percent incremental shareholder dilution. It did another follow on financing in 2003 with Rockwood for another 12.2 million shares at another 30% dilution to existing shareholders. It also invested in other technologies that failed to advance but caused dilution of the equity and diversion of cash resources. By 2007 the company had seven million dollars of senior debt due and payable and insufficient cash to pay off the debt holder. It also had successfully completed phase 2 testing on LS but had no money to advance the program let alone pay off the debt to its senior lender. The company was trading about where it is now and had 61 million shares outstanding for a market cap of \$13.6 million. It was at that time that I was introduced to the company. I was managing a life sciences fund for a multi-strategy hedge fund called Platinum. I agreed to invest \$13 million in stages to enable Navidea to pay off the note and to fund the phase 3 trial. We received approximately 70 million shares and warrants to buy shares which increased the shares outstanding by an incremental 100 %.

At this time, mid 2008, Navidea had 71 million shares outstanding and only 1 institutional investor, Platinum. As a multi-strategy hedge fund, Platinum was very liquidity driven and it sold over 40 million shares of Navidea stock at prices above \$3 per share. I left Platinum in 2013 not long after the board of Navidea did a highly dilutive equity financing with Crede Capital. In my opinion the board, management and especially its outside counsel failed to understand the terms of deal and sold shares to an institution at a price effectively 50% below the market price with warrants that were structured to enrich the investor if the share price dropped post financing. This is exactly what happened and this encouraged shorts to enter the stock in a very big way.

I believe that these steps led to a steep and rapid drop in the share price because there were no institutional buyers to support the stock in the aftermarket. While this was happening, the company was 3 years delayed in launching LS and committed massive cash, to develop in-licensed products including an imaging agent for Alzheimer's and a failed Parkinson's agent.

After this series of events, the BOD decided to let the CEO go. I was asked to step in as interim CEO, which I did for about six months until we found a CEO with experience launching and selling new specialty pharmaceutical products. BTW I accepted the job and did so without receiving one penny of cash compensation or one share or option for this full time commitment. By this time Lymphoseek was already significantly underperforming initial company guidance.

We had 2 members of the Board of Navidea who were ex Cardinal radio-pharmacy executives who felt that building our own salesforce to complement the Cardinal efforts would get the sales going and they were convinced that the CEO we eventually hired would make that happen. The CEO asked the board to approve the hiring of 16 sales people to supplement the Cardinal distribution effort and the board agreed. This more than doubled our annual expenses and required refinancing our debt and adding additional debt. The board was presented a set of projections that never came to fruition. The Company missed its minimum revenue target the very first year following the signing of the CRG deal. This was the beginning of the difficulty that ultimately led to the CRG lawsuit.

That summer in an effort to address the share price and the fact that there were no institutional buyers, management and the board, came up with a clever plan to address this problem. We listed the Navidea shares on the Tel Aviv stock exchange. The rationale was to take advantage of the fact that a 300 million market cap stock in the US was too small to attract institutional interest in the US, but if we listed in Israel we would be put in certain indexes and the Israeli pension funds etc would be required to buy our shares as part of their charter. Since we had no plans to raise money on the listing, the projected purchase of approximately 25-30 million shares should lift our market cap to above \$500 million where we would gain the same interest from US index linked funds. We got our market cap to over \$400 million a few weeks before the institutions would have to buy on the TASE but then Platinum, against their assurances to the company, sold about 15 million of the 25 to 30 million shares that we hoped would be bought in the open market.

From there we were hit with the CRG mess. While I will not review the sordid CRG situation other than to comment that the same lawyer who failed to understand the terms of the Crede deal also failed on numerous levels to provide the board and management with a heads up to the horribly one sided CRG terms, which potentially handed them control of the company for \$20 million in new debt, at a time the Company had a market cap of over \$200 million and as described above, exceeded \$400 million a few months post signing the CRG deal.

In the summer of 2016 I was asked again by the board to take on the CEO role but this time not as interim, but full time, since the board felt that in order to refinance the debt the Company needed an experienced and committed full time CEO. I agreed to a one year deal and agreed to take effectively the same compensation package as the recently departed CEO. In fact, I was effectively working full time to restructure the board and CEO and strategy and then refinance the CRG debt for a year before I assumed the role officially all with ZERO compensation.

Now we believe we are in an excellent place from a pipeline and strategy perspective but clearly we suffer from the technical aspects of having little or no institutional ownership, limited funds and no independent research coverage. We believe we have two options - do what most companies in our position do which is call a spade a spade, admit that our previous programs and strategies RIGGS, LS, our Alzheimer product, Parkinson's product, and other programs, some mentioned and other skipped, failed and reboot by bringing in fresh capital and cram down all existing investors to essentially nothing. We can do this because we believe we have some exciting pipeline products and while they will take a few years and a lot of money to fully develop, we believe that they do capture the interest of investors but they reasonably want to get paid for their stepping in and taking the new time and development risk. This is fine for existing and new management, because they can get new options and equity and guarantee their salary for the foreseeable future. Our Board and management do not believe that this path would be in the best interest of Navidea's existing investors especially those who cannot afford to invest in the offering.

The second option, which after careful deliberation, is what the current board and management believe is in the best interest of both Navidea and its stockholders, is to avoid any immediate, significant financings, until we can identify and educate new investors about the assets we have and why we believe they, new investors, should get involved in Navidea sooner than waiting for the pipeline to more fully mature. Despite the fact that this hasn't yet succeeded we believe that as the current trials come to completion and more data is disseminated to the market, new investors should be more encouraged by the company's future.

So if you look at the requests we have made in this light, based on the history of the company and more specifically, the experience the Navidea shareholders have with this management team and this Board, we think there are plenty of reasons, based on actions and words to provide the Company with the tools we believe are helpful and maybe even necessary, to continue down this path which is without a doubt, riskier to management and the board, but in our opinion based on discussions with bankers and IR professionals we have spoken with, clearly preferable to all existing investors.

To make this even easier for those concerned of potential conflicts, I will not be accepting a new contract at Navidea but will remain on the board. In addition, I am Navidea's largest single investor and I currently intend to retain my stake in the Company. I have also offered to extend out the \$2.5 million in debt the company currently owes me, which is more than 50% of its existing cash position, and I intend to present to the board with a proposal, that will include under certain conditions, the flexibility to be repaid in stock vs cash.

If the company pursues the first option, i.e., to do a highly dilutive offering near term with warrants, I have the most to lose as the largest single investor in Navidea stock. With respect to the request to add to the employee option plan, I will not get ANY new options, other than what all board members get, and we have sufficient options in the existing plan for BOD options for the foreseeable future. Both Navidea and I will get a benefit though from the approval to add more shares to the plan since that will enable the Company to satisfy my existing grant in shares vs cash but only IF the share price goes up 12 times AND since we can reasonably expect that the company will have to issue new shares in a financing before the price hits \$2.50 per share, the market cap will have to increase by greater than 12 times before I can participate on that grant. Stated in a different way the market cap of the company would have to exceed \$450 million before I receive ANY benefit from that grant. Clearly my interests will be aligned with current shareholders as the largest single investor in Navidea and that is without consideration for that grant. Why would I recommend actions that will hurt me along with all other existing Navidea investors and can't possibly help me? If the plan does not get approved in addition to the difficulties it causes, that Jed will enumerate, the company will have to pay me at least \$7.5 million in cash if the shares ever exceed \$2.50 a share which will be adjusted if there is a reverse split. The terms are all clearly laid out in the contract that was signed in September 2016. So if the maximum reverse split is done there is ZERO difference financially in how the grant is realized. After a 20 -1 reverse the share price will have to reach \$50 per share and I will have 250,000 options to exercise at \$20 per share. And if the reverse is approved but not the option plan the company will be at risk of the exact same amount, \$7.5 million dollars as pre-split. The advantage to me is I will get to exercise and hold the shares but then the advantage to Navidea is that I have to pay Navidea \$5 million dollars vs Navidea having to pay me \$7.5 million on demand if the option plan is not extended.

While I am not resigning today, I am working with the board and Jed, who I am recommending replace me as CEO. While I aim to make that happen in the near future, it will depend on our progress with Macrophage. My goal is to ultimately be able to focus all my energy full time on creating value at MT, which I believe is the most realistic way to add significant value to Navidea. Navidea's pipeline is full and I foresee the potential for real blockbusters in imaging NASH, Autoimmune diseases, CVD and cancer. We have already generated data on a level that, in my opinion, is equal to or better than the data that convinced me to invest in LS in 2007. I believe the commercial opportunities for these products are orders of magnitude greater than even the rosy projections I was provided for LS when I made my original investment. The strategy for advancing these assets is well developed and I am confident that Jed can lead the organization thru the development and partnering of these programs. I will be there with maximum skin in the game, to help in any way I can.

I will now turn the call over to Jed to explain the proxy issues in more detail.

Jed Latkin:

Thank you Michael, first I want to reiterate that despite the many conversations I have had, and continue to have with all the shareholders, we have also been focused on the package submission to the Food and Drug Administration regarding the activated macrophages and Rheumatoid Arthritis (RA) detection and monitoring.

As management focuses on these clinical developments, we can also now provide a clarification on the proxy. There are two topics of conversation regarding the proxy, the first being the option plan.

The option plan itself is for ALL (stressed) employees; meaning it will help Navidea attract the finest employees as we advance our programs, while helping the company retain the talent already in place. There will not be an issuance of new employee options to Dr. Goldberg at this time nor as you can see from the current Proxy have there been any since 2016 nor do we anticipate that there be any outside the board of directors' plan in the future.

If the plan isn't approved, the outcome will be the absence of shares available to give options to the staff and senior management. This could result in one of two scenarios, a) we are forced to pay larger cash sums to retain existing individuals and attract talent as needed or b) key players on the team leave for other opportunities with more material upside. We believe that using options to retain talent is a smart move for a company because it aligns the incentives of the employees with the shareholders. Employees that view options as an attractive compensation also view the company as having greater potential tomorrow than cash given today. Companies that are short cash and don't want to go into the market to raise funds frequently use these plans in lieu of upfront dilution at a lower stock price. Option plans are typically at or above market (and in mine and Michael's case SIGNIFICANTLY ABOVE MARKET) and therefore incent the workforce to focus solely on the success of the company.

The second topic of conversation at this time is the reverse split. We reviewed various options that could be put in place and decided on the current path for several reasons.

- As the reverse split will be completed in the future, we worked off of the issued shares at this time, to avoid a special proxy in the future. Mathematically if the full ratio was done we would be left with only 6 million shares in reserve and Navidea management believes it is important to have flexibility with the company's shares as to not dilute existing shareholders to a point where their ownership is minimal.
- 1) reserve and Navidea management believes it is important to have flexibility with the company's shares as to not dilute existing shareholders to a point where their ownership is minimal.
 - 2) The company's goal on this front is quite simple and easy to explain
 - a. to have enough shares for Navidea to be able to execute internally on the share option plan,
 - b. 401K match plan as we match up to a certain % of all employee 401k contributions with shares of Navidea stock (yet another way to align our employees goals with shareholders)
 - c. employee bonuses which this year were paid all in stock and last year were paid 50% in stock
 - d. in the past (for example the Cardinal deal where Navidea issued 10M warrants and 1M warrants to UCSD both priced at a \$1.50 exercise price) to facilitate further endeavors.
-

The Company would be able to put in place a potential standby equity line as well for continuous developmental support which would also facilitate a boost to the approval trial as the company would add more sites to the program.

Management would also have additional flexibility should it need it for other purposes to help protect shareholder value.

I can't stress enough the need to have this flexibility as it will be necessary once we have some significant good news to enact the reverse split, start seeking out street coverage once again and hopefully drive volumes up as well.

After the reverse split is complete the Company is going to look into reducing the overall number of Authorized shares for next year's annual meeting instead of having to do a special proxy.

With all that has gone on over the last three years and the pains that current management has gone through to maintain the Company and prevent it from being taken over or driven into bankruptcy we hope that shareholders know that we are committed to preserving and creating value and not diluting it. We believe the current price reflects more on the technical nature of microcap trading and the difficulty in getting investor attention to focus on the fundamentals and not a reflection of the value of the Company's assets and their potential.

Our objective is to hold off undertaking a significant financing until we have had a series of significant positive announcements, sufficient to attract investor interest to our pipeline of diagnostic products. This has been the plan and remains the plan, while we cannot guarantee the future, we can clearly express our strategy and commit to our investors that we remain optimistic enough to continue to work to achieve this goal. The goal being to attract institutional investors, in an effort to close the valuation gap, between the current market price and our assessment of value, so that we have the necessary flexibility and resources, to properly develop the blockbuster potential products we believe we have.

In addition we continue to believe that ultimately these products should be partnered to maximize their commercial potential we want the opportunity to negotiate partnerships from a position of relative strength and not with a gun pointed at our heads, so this flexibility will be key.

I want to reassure our shareholders once again that we will follow a path towards reverse split only when we see that it is absolutely the right time to do it.

Prior to opening up the floor to open Q&A I wanted to address the most frequently submitted shareholder questions:

Has any more progress been made in advancing the biomarker qualification process with the FDA than what was disclosed in last 10Q?

Yes. In the initial conferences with FDA regarding the biomarker qualification, the FDA pointed out their desire to narrow specific elements of the qualification and enhance the narrower elements with additional data. This has been completed. As previously noted, the FDA assigned a partner to work with Navidea on completing the qualification package to FDA and Navidea is completing the package with the FDA-assigned partner. This package includes the additional data and approaches to qualification.

2. Is extended NASH imaging study NAV3-30 completed? If so, is update forthcoming?

The extended imaging is near completion. However, Navidea intends to enroll all of the patients before the image analysis will be released. This is in keeping with standard parameters that govern clinical trials and eliminating the release of data as “anecdotes”.

3. Is Kaposi Sarcoma imaging study NAV3-24 still on target for August completion?

Yes. Navidea has completed the initial safety cohort in this study. Navidea has raised the level of this study to a Phase 2 study and has incorporated a biopsy assessment of the KS as a concordance marker with the imaging, and an analysis of “active” vs “inactive” KS. The study will continue to enroll AIDS and transplant patients with confirmed KS.

4. Can clarity be provided if the 15 mm (10+5) executive stock options to be authorized in proxy, under 2014 Plan, will also be reversed in R/S approved?

Yes the issued options would be reversed but not the unissued – so let's go through an example – Michael was issued 5mln those would be split, I was issued a total of 1mln over three years and those will be split as well and adjusted for the new price. The rest of the options would not be affected by the reverse since they haven't been issued to anyone yet.

5. Jed on reverse split would it be fair to hypothesize:

a. With NAVB's small market size and limited access to equity that NAVB has little negotiating leverage for strong win/win deals with either MT funders or NAVB JV's?

This is an excellent point, using our shares in negotiations has been key. One of our partners who has helped us develop go forward plans in several therapeutic areas took options struck at \$1.50 in lieu of a higher upfront payment. These options aren't cashless so when the stock passes \$1.50 the company will receive the money when they are exercised. More importantly it shows that partners are willing to share in the upside as they believe in the story.

Retaining a high number of authorized unissued shares, through the R/S, provides stronger negotiating leverage
b. with potential MT funders and JV partners, that projects that the science is very strong and that NAVB/MT (the shareholders) can and are willing to go it alone with actionable funding, if needed?

Yes, the ability to have access to markets acts as a great leverage point in the negotiations. While we have no intention of doing a large dilutive deal, a key negotiation point has to be the credible threat so to speak of being able to finance our operations on our own and pursue an independent commercial strategy if necessary.

I want to thank you for taking the time to dial in and I would like to now open the floor to Q&A.