# 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)	April 21, 2015	
NAV	IDEA BIOPHARMACEUTICALS, INC	C.
(Exact 1	name of registrant as specified in its cha	rter)
Delaware	001-35076	31-1080091
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)
5600 Blazer Parkway, Suite 20	00, Dublin, Ohio	43017
(Address of principal exec		(Zip Code)
Registrant's telephone number, including area code	(614) 793-7500	
(Former name	or former address, if changed since last	t report.)
Check the appropriate box below if the Form 8-K filiany of the following provisions (see General Instruct  ☐ Written communications pursuant to Rule 425 un  ☐ Soliciting material pursuant to Rule 14a-12 under  ☐ Pre-commencement communications pursuant to  ☐ Pre-commencement communications pursuant to	ion A.2. below):  der the Securities Act (17 CFR 230.425 the Exchange Act (17 CFR 240.14a-12 Rule 14d-2(b) under the Exchange Act	) (17 CFR 240.14d-2(b))

# Item 1.01 Entry Into a Material Definitive Agreement.

On April 21, 2015, Navidea Biopharmaceuticals, Inc. (the "Company") entered into an agreement (the "Termination Agreement") with Alseres Pharmaceuticals, Inc. ("Alseres") terminating the sub-license agreement between the parties dated July 31, 2012 (the "Sub-License Agreement"), relating to the Company's diagnostic product candidate known as NAV5001 (the "Licensed Product"). Pursuant to the Termination Agreement, the Sub-License Agreement will be terminated, and the Company will transfer to Alseres all regulatory materials, technical data, intellectual property and documentation relating to the Licensed Product. The Company has agreed to perform certain clinical support services for Alseres with respect to the Licensed Product on a cost-plus reimbursement basis.

The Termination Agreement provides for the payment by Alseres to Navidea of milestone payments with respect to the commercialization by Alseres of the Licensed Product, and for royalties commencing upon the first commercial sale of a Licensed Product anywhere in the world.

The foregoing description of the terms of the Termination Agreement is qualified in its entirety by reference to the text of the Termination Agreement, a copy of which is attached hereto as Exhibit 10.1, and incorporated herein by reference.

# Item 1.02 Termination of a Material Definitive Agreement.

The contents of Item 1.01 are incorporated by reference into this item.

#### Item 8.01 Other Events.

On April 27, 2015, the Company issued a press release regarding its entry into the Termination Agreement. A copy of the Company's April 27, 2015, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 8.01 of this Current Report on Form 8-K, including exhibit 99.1 attached hereto, shall not be treated as "filed" for purposes of the Securities Exchange Act of 1934, as amended.

#### Item 9.01 Financial Statements and Exhibits.

Exhibit Description

(d) Exhibits.

Exhibit	
<u>Number</u>	

99.1

Termination Agreement, dated April 21, 2015, by and between Navidea Biopharmaceuticals, Inc. and Alseres

Pharmaceuticals, Inc. (portions of this Exhibit have been omitted pursuant to a request for confidential treatment

and have been filed separately with the United States Securities and Exchange Commission).

Press Release, dated April 27, 2015, entitled "Navidea Divests NAV5001, a Non-Core, Development-Stage

Imaging Agent for Parkinson's Disease."

Statements contained or incorporated by reference in this Current Report on Form 8-K 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, and markets for the Company's products, are forward-looking statements. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors 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, 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, and other risks detailed in the Company's most recent Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

# **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: April 27, 2015

By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice President and
Chief Financial Officer

# CONFIDENTIAL TREATMENT REQUESTED PURSUANT TO RULE 24B-2

Certain confidential portions of this Exhibit, indicated by [\*], have been omitted pursuant to Rule 24b-2 of the Securities Exchange Act of 1934. The omitted materials have been filed separately with the U.S. Securities and Exchange Commission

AGREEMENT

**BETWEEN** 

NAVIDEA BIOPHARMACEUTICALS, INC.

AND

ALSERES PHARMACEUTICALS, INC.

#### **AGREEMENT**

This Agreement ("Agreement") is made and entered into effective April 21, 2015 (the "Effective Date") by and between Navidea Biopharmaceuticals, Inc., a Delaware corporation having an address at 5600 Blazer Parkway, Suite 200, Dublin, OH 43017-1367 ("NAVB") and Alseres Pharmaceuticals, Inc., a Delaware corporation having an address at 10 Rogers Street, Suite 101, Cambridge, MA 02142 ("ALSE"). Each of NAVB and ALSE may be referred to herein as a "Party" and collectively as the "Parties".

#### RECITALS

NAVB and ALSE entered into a sub-license agreement dated July 31, 2012;

NAVB and ALSE desire to terminate the sub-license agreement dated July 31, 2012 without prejudice;

NAVB has performed extensive development of a diagnostic product known as NAV5001 (also known as ALTROPANE) and acquired valuable know-how that can be used in further development;

NAVB and ALSE desire that this Agreement will affect the transfer of all data, clinical materials and regulatory files including but not limited to assignment of the Special Protocol Assessment Agreements covering the clinical testing of the Licensed Product;

NAVB and ALSE understand and agree that ALSE will form a new legal entity ("NEWCO") owned by ALSE to complete the development and commercialization of the Licensed Product;

NEWCO's development of the Licensed Product will be funded by Third Parties investing through debt, equity or similar transactions (the "Investors"); and

In consideration for the rights granted to ALSE herein, ALSE or NEWCO will make payments as set forth herein;

Now, therefore, in consideration of the recitals set forth above, the terms and conditions set forth below, and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties agree as follows:

#### ARTICLE 1. DEFINITIONS

For purposes of this Agreement, the following terms have the following meanings:

1.1. "Affiliate" means, with respect to any entity, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such entity. For this purpose, "control" means the ownership of fifty percent (50%) or more of the voting securities entitled to elect the directors or management of the entity, or the actual power to elect or direct the management or policies of the entity, whether by law, contract or otherwise. In any country where the local law does not permit foreign equity participation of at least fifty percent (50%), then an "Affiliate" includes any company in which an entity owns or controls or is owned or controlled by, directly or indirectly, the maximum percentage of outstanding stock or voting rights permitted by local law.

[*]	— in	dicates	deleted	language
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- 1.2. "Challenge" means any challenge to the validity or enforceability of any of the Licensed Patents before any administrative, judicial or other governmental authority, court, tribunal or arbitration panel, including by (i) filing a declaratory judgment action in which any of the Licensed Patents is alleged to be invalid or unenforceable; (ii) citing prior art pursuant to 35 U.S.C. § 301, filing a request for re-examination of any of the Licensed Patents pursuant to 35 U.S.C. § 302 and/or § 311, or provoking or becoming a party to an interference with an application for any of the Licensed Patents or any derivation proceeding pursuant to 35 U.S.C. § 135; or (iii) filing or commencing any re-examination, opposition, *inter partes* review, other review, cancellation, nullity or similar proceedings against any of the Licensed Patents in any country.
- 1.3. "Commercialization" or "Commercialize" means any and all activities directed to the offering for sale and sale of a Licensed Product, including, (i) activities directed to marketing, promoting, detailing, distributing, manufacturing, importing, selling and offering to sell such Licensed Product, (ii) interacting with regulatory authorities regarding any of the foregoing and (iii) seeking pricing approvals and reimbursement approvals for such Licensed Product. When used as a verb, "Commercialize" means to engage in Commercialization and "Commercialized" has a corresponding meaning.
- 1.4. "Commercially Reasonable Efforts" means those efforts and resources that a similarly situated pharmaceutical company would reasonably devote in the exercise of its commercially reasonable practices relating to a product owned by it or to which it has rights of the type licensed hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account the competitiveness of the global and local marketplace, the pricing and launching strategy for the respective product, the proprietary position of the product, the profitability (but not considering any payments due to either Party pursuant to this Agreement) and the relative potential safety and efficacy of the product and other relevant factors, including technical, legal, scientific, regulatory or medical factors.
- 1.5. "Confidential Information" of a Party means all non-public information, whether written or oral, tangible or intangible, that is made available, disclosed, or otherwise made known to by or on behalf of such party to the other Party or its employees as contemplated under this Agreement.
- 1.6. "Control" means, with respect to any Know-How, Patent, or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the transfer in Article 3), to grant a license, Sublicense or other right (including the right to reference Regulatory Filings) to or under such Know-How, Patent, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party. "Control", "Controls", and "Controlled" have corresponding meanings.

- 1.7. "Field" means all diagnostic uses of the Licensed Product, and specifically includes diagnostic uses for differential diagnosis of Parkinsonian syndromes, including Parkinson's disease (PD) and other movement disorders, as well as Dementia with Lewy Bodies (DLB).
- 1.8. "Improvements" means any and all enhancements, modifications, corrections, inventions, changes or innovations made to the inventions claimed in the Licensed Patents, the Licensed Know-How or the Licensed Products created, developed or reduced to practice by or on behalf of ALSE or NEWCO.
  - 1.9. "Intellectual Property" means the Licensed Know-How and the Licensed Patents.
- 1.10. "Know-How" means any technical, scientific and business information including all biological, chemical, pharmacological, toxicological, clinical, and assay information, data, analyses, discoveries, inventions, methods, techniques, improvements, concepts, designs, processes, formulae, specifications and trade secrets, whether or not patentable, necessary or useful to develop, make, use or sell Licensed Product. Know-How shall also include documents (which shall include paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM and any other media on which the foregoing information can be stored) containing any of the foregoing information.
- 1.11. "Licensed Know-How" means any and all Know-How (including all Improvements) Controlled by NAVB as of the Effective Date related to diagnostic uses for differential diagnosis of Parkinsonian syndromes, including Parkinson's disease (PD) and other movement disorders, as well as Dementia with Lewy Bodies (DLB).
- 1.12. "Licensed Patents" means: (a) the Patents listed in <u>Exhibit A</u>; (b) any patent issuing on any such Patents listed in <u>Exhibit A</u>; and (c) all applications and patents claiming priority to or having common priority with (a) and/or (b) including foreign counterparts (including supplementary protection certificates) to any such patent rights.
- 1.13. "Licensed Product" means any product, material, kit, service, process or procedure that if discovered, developed, made, used or sold in the absence of the grants in this Agreement would utilize Licensed Know-How and/or Licensed Patents and specifically includes [123I]-E-IACFT (also known as ALTROPANE and as NAV5001).
- 1.14. "Net Sales" means the consideration for the sale, by ALSE or its affiliates or Sublicensees, of Licensed Products covered by Licensed Patents or Licensed Know-How, less documented qualifying costs borne by the seller that were directly attributable to the sale and identified on the invoice. Qualifying costs are limited to: customary discounts; reasonable credits or refunds for claims or returns; prepaid outbound transportation expenses and insurance; and sales and use taxes imposed by governmental agencies.
- 1.15. "Patents" means (i) all national, regional and international patents and patent applications, including provisional patent applications, that are listed in <u>Exhibit A.</u> (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention, (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, reexaminations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii), and (iii)) and (v) any similar rights.

- 1.16. "Regulatory Filing" means any filing with, or submission to, any governmental authority or non-governmental pricing or reimbursement authority that regulates or otherwise exercises authority with respect to the development, manufacture or Commercialization of Licensed Products or any regulatory application or other document relating to Licensed Products.
- 1.17. "Regulatory Materials" means the technical, medical and scientific information NAVB provided to the U.S. Food and Drug Administration ("FDA") as submissions to the Licensed Product Investigational New Drug Application ("IND") together with all related correspondence and rights to or from FDA including but not limited to any Special Protocol Assessment Agreements covering the Licensed Product.
- 1.18. "Sublicense" means a grant by ALSE to a Third Party of any sublicense, or option to sublicense, under the licenses granted to ALSE under this Agreement.
- 1.19. "Sublicensee" means a Third Party to whom a Sublicense is granted. For the avoidance of doubt, Sublicensee includes any arm's length Third Party distributor ("Distributor") to which ALSE or any of its Sublicensees sells a Licensed Product for resale of Licensed Product by the Distributor, and where Distributor has no other rights other than to promote, manufacture, distribute or resell Licensed Product.
- 1.20. "Term" means a time commencing on the Effective Date, which will expire on a country-by-country and Licensed Product-by-Licensed Product basis on the date of expiration of the last to expire Valid Claim in the Licensed Patents covering such Licensed Product in such country.
  - 1.21. "Territory" means worldwide to the extent this license may legally be granted.
  - 1.22. "Third Party" means any individual or entity other than ALSE or NAVB or an Affiliate of ALSE or NAVB.
- 1.23. "Valid Claim" means, with respect to the Patents: (a) a claim in an issued patent which has not (i) expired, (ii) been finally adjudicated or admitted as invalid or unenforceable, or (iii) been abandoned; or (b) a claim in a pending application.

# ARTICLE 2. TERMINATION OF SUB-LICENSE

- 2.1. The sub-license agreement dated July 31, 2012 between NAVB and ALSE ("Sub-License Agreement") is terminated without prejudice.
  - 2.2. NAVB agrees that it will have no further rights in or to the Licensed Product except as set forth in this Agreement.

2.3. Both parties agree that each will take no action against the other for breach of the Sub-License Agreement.

# ARTICLE 3. TRANSFER OF MATERIALS

- 3.1. During the ninety (90) day period following the Effective Date, NAVB shall use Commercially Reasonable Efforts to return to ALSE all documents in NAVB's possession or under its Control relating to the Licensed Product or the Regulatory Materials.
- 3.2. NAVB hereby irrevocably assigns to ALSE all of NAVB's right, title and interest in and to any Regulatory Materials for Licensed Products including, but not limited to, the IND therefor and any foreign equivalents. Thereafter, ALSE or its Sublicensees shall hold title to such IND (and foreign equivalents), and shall assume full responsibility for such IND (and foreign equivalents).
- 3.3. Following the Effective Date, but not later than thirty (30) days after the Effective Date, NAVB shall execute any and all other instruments, forms of assignment or other documents and take such further actions as required and requested by ALSE to give effect to or evidence the foregoing assignment in Article 3.2.
- 3.4. NAVB hereby irrevocably transfers to ALSE all of its rights title and interest in and to the Licensed Know-How Controlled by NAVB as of the Effective Date which is necessary or useful to develop or commercialize Licensed Products.

# **ARTICLE 4. SERVICES**

NAVB agrees at the request of ALSE or NEWCO to perform Licensed Product development in the licensed Field for the six month period beginning on the Effective Date (the "Transfer Period") at [\*] for NAVB's staff working on development. ALSE or NEWCO will pay NAVB's out-of-pocket cost for vendors, including the contract manufacturer and investigational sites as pass through costs only insofar as such expenses were requested by ALSE or NEWCO and incurred subsequent to the Effective Date, with the exception that within 20 working days of the Effective Date ALSE or NEWCO will reimburse NAVB on a fully documented pass-through basis for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. If ALSE or NEWCO requires NAVB services subsequent to the Transfer Period, all research and development will be charged at [\*] In performing Services, NAVB will comply with all US laws.

5.1. ARTICLE 5. NAVB RETAINED RIGHTS. NAVB retains all rights necessary for rendering the services and obligations as set forth in this Agreement.

# ARTICLE 7. REPORTS, RECORDS AND PAYMENTS

- 7.1 Reports.
- (a) Progress Reports.
  - (i) Beginning on December 31 of the calendar year after the Effective Date and ending on the earlier of the payment of the milestone due under Section 7.3(c) or the date of the first commercial sale of a Licensed Product in the United States, ALSE shall report yearly to NAVB ALSE's (and Affiliate's and Sublicensee's) activities for the preceding twelve (12) months to develop and test all Licensed Products and obtain governmental approvals necessary for marketing the same. Such annual reports shall be due within thirty (30) days of the reporting period and include a summary of work completed, summary of work in progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Products, and summary of resources (dollar value) spent in the reporting period. The reports referred to in this Article 7.1(a)(i) should be marked with the following title: "Agreement between Navidea Biopharmaceuticals, Inc. and Alseres Pharmaceuticals, Inc.". Reports shall be submitted as attachment to NAVB's email address: [\*].

- (ii) ALSE shall report to NAVB the date of a first commercial sale of a Licensed Product anywhere in the Territory.
- (b) **Royalty Reports.** After the first commercial sale of a Licensed Product anywhere in the Territory, ALSE shall, unless the payment specified in Section 7.3(b) extinguishing the royalty obligation is made by ALSE, submit to NAVB yearly reports beginning on December 31 of the calendar year after the first commercial sale of a Licensed Product. Each royalty report shall cover ALSE's (and each Affiliate's and Sublicensee's) most recently completed calendar year and shall show:
  - (i) the amounts of payments to Investors towards the royalties and/or other compensation payments set forth in Article 7.3(b)(ii);
  - (ii) the date of first commercial sale of a Licensed Product in each country in the Territory;
  - (iii) gross sales, deductions, and net sales during the most recently completed calendar year and the royalties, in US dollars, payable with respect thereto;
  - (iv) the number of each type of Licensed Product sold;
  - fees and royalties received during the most recently completed calendar year in US dollars, and the portion thereof payable to NAVB hereunder;
  - (vi) the method used to calculate the royalties; and
  - (vii) the exchange rates used.

If no sales of Licensed Products have been made and no Sublicense revenue has been received by ALSE during any reporting period, ALSE shall so report. The reports referred to in this Article 7.1(b) should be marked with the following title: "Agreement between Navidea Biopharmaceuticals, Inc. and Alseres Pharmaceuticals, Inc.". Reports shall be submitted as attachment to NAVB's email address: [\*].

[\*] – indicates deleted language

#### 7.2 Records & Audits.

- (a) ALSE shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct records of all Licensed Products manufactured, used, and sold, and other fees received under this Agreement. Such records shall be retained by ALSE for at least five (5) years following a given reporting period.
- (b) Upon five (5) business days prior notice to ALSE all records shall be available during normal business hours for inspection at the expense of NAVB by NAVB's Internal Audit Department or by a Certified Public Accountant selected by NAVB and in compliance with the other terms of this Agreement for the sole purpose of verifying reports and payments or other compliance issues. Such inspector shall not disclose to NAVB any information other than information relating to the accuracy of reports and payments made under this Agreement or other compliance issues. In the event that any such inspection shows an under reporting and underpayment in excess of five percent (5%) for any twelve-month (12-month) period, then ALSE shall pay the cost of the audit as well as any additional sum that would have been payable to NAVB had the ALSE reported correctly, plus an interest charge at a rate of ten percent (10%) per year. Such interest shall be calculated from the date the correct payment was due to NAVB up to the date when such payment is actually made by ALSE. For underpayment not in excess of five percent (5%) for any twelve-month (12-month) period, ALSE shall pay the difference within thirty (30) days without interest charge or inspection cost. NAVB may only conduct one such audit per calendar year.

# 7.3 Payments.

(a) All fees, reimbursements and royalties due to NAVB shall be paid in United States dollars and all checks shall be made payable to "Navidea Biopharmaceuticals, Inc.", referencing NAVB's taxpayer identification number, 31-1080091, and sent to NAVB according to Article 12.1. When Licensed Products are sold in currencies other than United States dollars, ALSE shall first determine the earned royalty in the currency of the country in which Licensed Products were sold and then convert the amount into equivalent United States funds, using the exchange rate quoted in the Wall Street Journal on the last business day of the applicable reporting period.

# (b) Royalty Payments.

- (i) Royalties shall accrue when Licensed Products are invoiced, or if not invoiced, when delivered to a Third Party.
- (ii) NAVB will be entitled to a royalty of [\*]% of Net Sales with such payment obligation to commence immediately after NEWCO's Investors have been paid royalties and/or other compensation equal to three (3) times their initial investment that established NEWCO. ALSE retains the right at any time to extinguish any future royalty obligation to NAVB by making a one-time cash payment of [\*] to NAVB. For the sake of clarity, such payment may not be made prior to payment of the milestone payment described in Article 7.3(c).

- (iii) ALSE shall pay earned royalties quarterly on or before February 28, May 31, August 31 and November 30 of each calendar year. Each such payment shall be for earned royalties accrued within ALSE's most recently completed calendar quarter.
- (iv) Royalties earned on sales occurring or under a Sublicense granted pursuant to this Agreement in any country outside the United States shall not be reduced by ALSE for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income, except that all payments made by ALSE in fulfillment of NAVB's tax liability in any particular country may be credited against earned royalties or fees due NAVB for that country. ALSE shall pay all bank charges resulting from the transfer of such royalty payments.
- (v) If at any time legal restrictions prevent the prompt remittance of part or all royalties by ALSE with respect to any country where a Licensed Product is sold or a Sublicense is granted pursuant to this Agreement, ALSE shall convert the amount owed to NAVB into U.S. currency and shall pay NAVB directly from its U.S. sources of funds for as long as the legal restrictions apply.
- (vi) To the extent all of the Patents and Know-How are completely covered by any license to the U.S. Government and the Government exercises its March-in rights under 35 USC Section 203, ALSE's royalties shall be reduced to the level set by the Government.
- (vii) In the event that any patent or patent claim within Patent Rights is held invalid in a final decision by a patent office from which no appeal or additional patent prosecution has been or can be taken, or by a court of competent jurisdiction and last resort and from which no appeal has or can be taken, all obligation to pay royalties based solely on that patent or claim shall cease as of the date of such final decision. ALSE shall not, however, be relieved from paying any royalties that: accrued before the date of such final decision, are based on another patent or claim not involved in such final decision, or are based in any manner on the use of Know-How.
- (viii) Royalty payments, recoveries and settlements, and royalty reports shall be rendered for any and all Licensed Products even if due after expiration of the Agreement.
- (c) Milestone Payments. ALSE shall also pay to NAVB a milestone payment of [\*] due and payable to NAVB upon the earlier of (i) completion by ALSE or ALSE's Sublicensees of a commercial transaction (apart from the debt, equity or other transactions contemplated to finance the development of the Licensed Product) which results in gross proceeds to ALSE or ALSE's Sublicensee of at least [\*] or (ii) 6 months after approval by the U.S. Food and Drug Administration of a NDA covering the Licensed Product.

I	[*]	l _	ind	dicates	deleted	language

- (d) **Term of Royalties.** The royalty obligations under Article 7.3(b) will terminate on the earlier of payment by ALSE of the [\*] payment under Article 7.3(b)(ii), or upon the expiration of the last to expire Licensed Patents.
- (e) Late Payments. In the event royalty, reimbursement and/or fee payments are not received by NAVB when due, ALSE shall pay to NAVB interest charges at a rate of ten percent (10%) per year. Such interest shall be calculated from the date payment was due until actually received by NAVB.

# **ARTICLE 8. PATENT MATTERS**

- 8.1 Patent Prosecution and Maintenance.
- (a) NAVB agrees that, from and after the Effective Date, ALSE will have the right, but not the obligation, to file, prosecute and maintain, in the name of ALSE, the Licensed Patents. ALSE will have the right to abandon any Licensed Patents or allow any issued Licensed Patent to lapse.

#### ARTICLE 9. GOVERNMENTAL MATTERS

9.1 **Governmental Approval or Registration.** If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, ALSE shall assume all legal obligations to do so. ALSE shall notify NAVB if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. ALSE shall make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

# ARTICLE 10. WARRANTIES, RELEASE, INDEMNIFICATION

Limited Warranty. Each Party represents and warrants to the other Party that it has full corporate power and authority to execute, deliver, and perform this Agreement, and that no other corporate proceedings by such Party are necessary to authorize the Party's execution or delivery of this Agreement. Without limiting the generality of the foregoing, NAVB hereby represents, and warrants to ALSE as follows: (i) NAVB is not aware of, and has received no notice that, the Know-How, Licensed Products, and Patent Rights infringes a valid claim of a Third Party's patent or infringes, misappropriates or otherwise violates a Third Party's valid intellectual property rights; (ii) NAVB is the owner, co-owner, or exclusive licensee in the Field of the Know-How and Patent Rights, and to the knowledge of NAVB, no Third Party has any claim in or to any of the Know-How or Patent Rights other than set forth in this Agreement; and (iii) there is no suit, claim or action pending, or to the knowledge of NAVB threatened, which would affect in any way the execution, delivery and performance of this Agreement by NAVB or the grant of any of the rights and privileges to ALSE hereunder.

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- Mutual **Release**. For itself and its employees, each of ALSE and NAVB hereby releases the other from any suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) (collectively, "**Losses**") relating to the Sublicense Agreement or relating to or arising out of the development, manufacture, use, sale, Commercialization or other disposition of a Licensed Product by ALSE or any of its Affiliates or Sublicensees. The foregoing does not constitute a release of either partyby the other for the breach of any covenant, representation or warranty set forth in this Agreement.
- ALSE's Indemnification. ALSE shall indemnify, defend, and hold NAVB harmless from all Losses resulting from any claim related to any event occurring after the Effective Date brought by a Third Party that relates to, or arises out of, the development, manufacture, use, sale, Commercialization or other disposition of a Licensed Product made by or on behalf of ALSE or any of its Affiliates or Sublicensees, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to Licensed Products made by or on behalf of ALSE or any of its Affiliates or Sublicensees. NAVB shall provide ALSE with prompt notice of any claim (with a description of the claim and the nature and amount of any such loss) giving rise to the indemnification obligation pursuant to this Article 10.3 and the exclusive ability to defend such claim (with the reasonable cooperation of NAVB). NAVB shall have the right to retain its own counsel, at its own expense, if representation by ALSE'S counsel would be inappropriate due to actual or potential differing interests between the Parties. Neither Party shall settle or consent to the entry of any judgment with respect to any claim for Losses for which indemnification is sought without the prior written consent of the other Party (not to be unreasonably withheld or delayed); provided, however, that ALSE shall have the right to settle or compromise any claim for Losses without such prior written consent if the settlement or compromise provides for a full and unconditional release of NAVB and is not materially prejudicial to any of NAVB'S rights. ALSE'S obligation to indemnify NAVB pursuant to this Article 10.3 shall not apply to the extent of any Losses that (i) arise from the negligence, recklessness, or intentional misconduct of NAVB; or (ii) arise from the breach by NAVB of any obligation, representation, warranty or covenant in this Agreement.
- 10.4 NAVB's Indemnification . NAVB shall indemnify, defend, and hold ALSE harmless from all Losses resulting from any claim related to any event occurring between July 31, 2012 and the Effective Date and arising out of any independent activities of NAVB brought by a Third Party that relates to, or arises out of, the development, manufacture, use, sale, Commercialization or other disposition of a Licensed Product made by or on behalf of NAVB or any of its Affiliates or Sublicensees, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to Licensed Products made by or on behalf of NAVB after July 31, 2012 and before the Effective Date. ALSE shall provide NAVB with prompt notice of any claim (with a description of the claim and the nature and amount of any such loss) giving rise to the indemnification obligation pursuant to this Article 10.4 and the exclusive ability to defend such claim (with the reasonable cooperation of ALSE). ALSE shall have the right to retain its own counsel, at its own expense, if representation by NAVB'S counsel would be inappropriate due to actual or potential differing interests between the Parties. Neither Party shall settle or consent to the entry of any judgment with respect to any claim for Losses for which indemnification is sought without the prior written consent of the other Party (not to be unreasonably withheld or delayed); provided, however, that NAVB shall have the right to settle or compromise any claim for Losses without such prior written consent if the settlement or compromise provides for a full and unconditional release of ALSE and is not materially prejudicial to any of ALSE'S rights. NAVB'S obligation to indemnify ALSE pursuant to this Article 10.4 shall not apply to the extent of any Losses that (i) arise from the negligence, recklessness, or intentional misconduct of ALSE; or (ii) arise from the breach by ALSE of any obligation, representation, warranty or covenant in this Agreement.

- 1 0 . 5 Disclaimers. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN ARTICLE 10.1 OF THIS AGREEMENT, NAVB AND ALSE DISCLAIM AND EXCLUDE ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH LICENSED PRODUCT AND THE INTELLECTUAL PROPERTY, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF PATENT VALIDITY, NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.
- 1 0 . 6 Damages. EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND EXCEPT FOR THE INDEMNITIES IN ARTICLES 10.3 AND 10.4, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OF ANY KIND.

# ARTICLE 11. CONFIDENTIALITY AND USE OF NAME

- shall (i) maintain in confidence such Confidential Information using not less than the efforts such Recipient uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of efforts; (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the Discloser, except for disclosures expressly permitted below; and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement. The obligations of non-disclosure and non-use under this Article 11.1 shall be in full force during the Term and for a period of five (5) years thereafter. Each Party, upon the request of the other Party, will return all copies of or destroy (and certify such destruction in writing) the Confidential Information disclosed or transferred to it by the other Party pursuant to this Agreement, within sixty (60) days of such request or, if earlier, the termination or expiration of this Agreement.
- The obligations in Article 11.1 shall not apply to any portion of the Confidential Information of the Discloser that the Recipient can show by competent written proof: (i) is subsequently disclosed to the Recipient by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use; (ii) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Recipient, without any breach by the Recipient of its obligations hereunder; or (iii) is independently developed by or for the Recipient without reference to or reliance upon the Discloser's Confidential Information.

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- 11.3 Notwithstanding Article 11.1 the Recipient may disclose Confidential Information belonging to the Discloser to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances: (i) complying with applicable laws and with judicial process, if in the reasonable opinion of the Recipient's counsel, such disclosure is necessary for such compliance; provided that Recipient timely notifies Discloser of Recipient's intent with sufficient time to permit Discloser to challenge such a disclosure before the court and (ii) disclosure of the other Party's Confidential Information to any of its officers, employees, consultants, or agents if and only to the extent necessary to carry out its responsibilities or exercise its rights under this Agreement; *provided* that each such disclosure under clause (ii) is bound by written confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement.
- No provision of this Agreement grants ALSE, its Affiliates or any Sublicensee any right or license to use the name of NAVB or the names or identities of any employee of NAVB without the prior written consent of NAVB. ALSE and its Affiliates and Sublicensees may, however, factually disclose that they benefit from a license from NAVB, or a Sublicense, under the Licensed Know-How and Licensed Patents.

# ARTICLE 12. MISCELLANEOUS PROVISIONS

- 12.1 **Correspondence.** Any notice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:
  - (a) on the date of delivery if delivered in person,
  - (b) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party, or
  - (c) upon confirmation by recognized national overnight courier, confirmed facsimile transmission, or confirmed electronic mail, to the following addresses or facsimile numbers of the parties.

# If sent to NAVB:

Navidea Biopharmaceuticals, Inc. 5600 Blazer Parkway, Suite 200 Dublin, OH 43017-1367 Attention: President, CEO Phone: 614-793-7500

Fax: 614-793-7522

# If sent to ALSE by mail:

Alseres Pharmaceuticals, Inc. 10 Rogers Street, Suite 101 Cambridge, MA 02142 Attention: President, CEO

- Assignment. Either Party, without the prior approval of the other Party, may assign all of its rights to a Third Party if the assignment is made to such Third Party as a part of, and in connection with, (i) the sale by the assigning Party of all or substantially all of its assets to which this Agreement relates to the Third Party; (ii) the sale, transfer, or exchange by the shareholders, partners, or equity owners of the assigning Party of a majority interest in the assigning Party to the Third Party; or (iii) the merger of the assigning Party into the Third Party (or a Third Party into the assigning Party). The assigning Party shall deliver to the other Party written notice of any such permitted assignment. This Agreement will inure to the benefit of ALSE and NAVB and their respective successors and assigns.
- 12.3 **No Waiver.** No waiver by either party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.
- Failure to Perform. In the event of a failure of performance due under this Agreement and if it becomes necessary for either party to undertake legal action against the other on account thereof, then the prevailing party shall be entitled to reasonable attorneys' fees in addition to costs and necessary disbursements.
- 12.5 **Force Majeure.** A party to this Agreement may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, the non-performing party's obligations herein shall resume.
- Amendment and Waiver. This Agreement may be amended from time to time only by a written instrument signed by the Parties. No term or provision of this Agreement will be waived and no breach excused unless such waiver or consent will be in writing and signed by the Party claimed to have waived or consented. No waiver of a breach will be deemed to be a waiver of a different or subsequent breach.
- 12.7 **Consents and Approvals.** Except as otherwise expressly provided, all consents or approvals required under the terms of this Agreement must be in writing and delivered as set forth in Article 12.1.
- 1 2 . 8 **Construction.** The headings preceding and labeling the paragraphs of this Agreement are for the purpose of identification only and will not in any event be used for the purpose of construction or interpretation of this Agreement.

- Enforceability. If a court of competent jurisdiction adjudges a provision of this Agreement unenforceable, invalid, or void, such determination will not impair the enforceability of any of the remaining provisions hereof and the provisions will remain in full force and effect so long as the Agreement, taking into account said voided provision, continues to provide the Parties with materially the same benefits as intended on the Effective Date. If the Parties are unable to realize materially the same benefits as contemplated on the Effective Date, the Parties shall negotiate in good faith to amend this Agreement to reestablish (to the extent legally permissible) such benefits.
- 12.10 **Third Party Beneficiaries.** No provision of this Agreement, express or implied, confers upon any Third Party any rights, remedies, obligations, or liabilities hereunder.
- 12.11 **Publicity.** Neither Party shall make any public statement or pronouncement of the execution of this Agreement, nor any of its terms, without the prior written consent of the other Party not unreasonably withheld or delayed.
- Relationship of the Parties. In entering into, and performing their duties under this Agreement, the Parties are acting as independent contractors and independent employers. No provision of this Agreement shall create or be construed as creating a partnership, joint venture, or agency relationship between the Parties. No party shall have the authority to act for or bind the other Party in any respect.
- 12.13 **Governing Laws.** This Agreement shall be interpreted and construed in accordance with the laws of the state of Delaware, but the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of the patent or patent application.
- 12.14 **Entire Agreement.** This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof. This Agreement (including all attachments, exhibits, and amendments) is the final and complete understanding between the Parties concerning the subject matter of this Agreement. This Agreement supersedes any and all prior or contemporaneous negotiations, representations and understandings, whether written or oral, concerning its subject matter. This Agreement may not be modified in any manner, except by written agreement signed by an authorized representative of both Parties. This Agreement may be executed in one or more counterparts, each of which when taken together shall constitute one and the same agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by their respective authorized officers as of the day and year written.

Navidea Biopharmaceuticals, Inc.		Alseres Pharmaceuticals, Inc.		
By:	/s/ Ricardo Gonzalez	By:	/s/ Peter Savas	
Name:	Ricardo Gonzalez	Name:	Peter Savas	
Title:	President & CEO	Title:	Chairman & CEO	
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[*] – indicates deleted language				

# EXHIBIT A

# PATENT SCHEDULE

US Patent Number 8,084,018
Canadian Application CA 2700468 (pending)
European Application EP 2219682 (pending)
Japanese Application JP 2014148529 (pending)
Japanese Application JP 2011502130 (removal of consideration before appeal)
US Application Number 60/984,163
PCT/CA2008/001916
US Patent Number 8,574,545

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# Press Release

#### FOR IMMEDIATE RELEASE

# Navidea Divests NAV5001, a Non-Core, Development-Stage Imaging Agent for Parkinson's Disease

– Company continues sharpened focus on commercialization of Lymphoseek<sup>®</sup> and development of its proprietary CD206-targeted Manocept<sup>TM</sup> platform –

DUBLIN OHIO, April 27, 2015 - Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced that it has entered into an agreement with Alseres Pharmaceuticals, Inc. to terminate the sub-license agreement dated July 31, 2012 for research, development and commercialization of NAV5001, an agent in Phase 3 clinical development for early detection of Parkinson's disease. Navidea previously announced its intention to decrease its R&D expenses by divesting its non-core neuroimaging assets. This agreement follows through on the Company's commitment to decrease cash burn while moving these neuroimaging programs forward.

"As part of the a strategic realignment that began in early 2014, we have re-focused our resources on the Manocept<sup>TM</sup> platform, specifically, commercialization of Lymphoseek ® and development of immuno-oncology therapeutics targeting activated and tumor-associated macrophages implicated in cancer," said Rick Gonzalez, President and CEO of Navidea. "Divesting NAV5001 is consistent with this strategy, substantially reduces Navidea's R&D expense obligations, allows the Company to maintain economic upside, and assigns the product's rights to an entity we believe has the capability to gain FDA approval."

Under the terms of this agreement, Navidea will transfer the NAV5001 IND, all data, clinical materials, regulatory files (including the Special Protocol Assessment agreements), patents, know-how, and other assets covering the clinical testing of the NAV5001 to Alseres. Alseres will reimburse Navidea on a fully-documented, pass-through basis for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, as requested by Alseres, Navidea will supply clinical support services for NAV5001 on a cost-plus reimbursement basis. In consideration for the rights granted to Alseres, Navidea will receive a milestone payment in connection with NAV5001's NDA approval by the U.S. FDA and a royalty on subsequent net sales of NAV5001.

# About Navidea Biopharmaceuticals, Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a commercial stage precision medicine company focused on the development and commercialization of precision diagnostics, therapeutics and radiopharmaceutical agents. Navidea is developing multiple precision-targeted products and platforms including Manocept<sup>TM</sup>, NAV4694, and NAV5001, to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and by the EMA in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and therapeutics, and advancing the Company's pipeline through global partnering and commercialization efforts. For more information, please visit www.navidea.com.

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# NAVIDEA BIOPHARMACEUTICALS

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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 news release, 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. Investors 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. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

#### Contact:

Source: Navidea Biopharmaceuticals, Inc.

Navidea Biopharmaceuticals

Investors

Tom Baker, 617-532-0624

tbaker@navidea.com

or

Media

Sharon Correia, 978-655-2686

Associate Director, Corporate Communications

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