

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

NAVIDEA BIOPHARMACEUTICALS, INC.

CIK:[810509](#) | IRS No.: **311080091** | State of Incorporation: **DE** | Fiscal Year End: **1231**
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SIC: **2835** In vitro & in vivo diagnostic substances

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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) May 10, 2013

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35076</u> (Commission File Number)	<u>31-1080091</u> (IRS Employer Identification No.)
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<u>425 Metro Place North, Suite 450, Dublin, Ohio</u> (Address of principal executive offices)	<u>43017</u> (Zip Code)
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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))

Item 1.01. Entry into a Material Definitive Agreement.

On May 10, 2013, Navidea Biopharmaceuticals, Inc. (the “Company”) entered into a clinical supply agreement (the “Supply Agreement”) with Nordion (Canada,) Inc. (“Nordion”). The Supply Agreement focuses on Nordion’s cGMP manufacturing and supply of NAV5001 clinical trial material to be produced at Nordion’s Vancouver, British Columbia, facility. Accordingly, Nordion will radiolabel the Company’s precursor drug product with Iodine-123 to form [¹²³I]NAV5001, manage the logistics and make arrangements for shipment of [¹²³I]NAV5001 to third-party clinical trial sites on behalf of the Company. [¹²³I]NAV5001 is a single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson’s disease and other movement disorders. The Supply Agreement has a term which commenced on May 10, 2013 (the “Effective Date”), and, unless earlier terminated as provided pursuant to its terms, which will expire three years after the Effective Date.

In consideration for the services provided by Nordion, the Company paid Nordion an initial amount upon the execution of the Supply Agreement, and will pay Nordion: (1) additional amounts upon Nordion’s achievement of milestones associated with the return to operation of the Nordion facility for purposes of manufacturing a supply of [¹²³I]NAV5001 for the Company’s use in clinical trials; and (2) a price per batch of [¹²³I]NAV5001 manufactured pursuant to the Supply Agreement. Commencing in the full first month following the completion of the Nordion facility and its readiness to manufacture [¹²³I]NAV5001, the Company will have an obligation to purchase a minimum amount of [¹²³I]NAV5001 from Nordion. If the Company fails to meet its minimum purchase obligations, Nordion may suspend its manufacturing operations at the facility and terminate the Supply Agreement. During the effective term of the Supply Agreement Nordion will not produce [¹²³I]NAV5001 for, or sell or provide [¹²³I]NAV5001 to, any third-party, except as instructed by the Company.

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

Item 8.01 Other Events.

On May 15, 2013, the Company issued a press release announcing that it had entered into the Supply Agreement with Nordion to produce and supply ¹²³I-labeled NAV5001 for the Company’s late-phase clinical trials. A copy of the complete text of the Company’s May 15, 2013, press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<i>Exhibit Number</i>	<i>Exhibit Description</i>
10.1	[¹²³ I]NAV5001 Clinical Supply Agreement, dated May 10, 2013, by and between Nordion (Canada) Inc. and Navidea Biopharmaceuticals, 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).
99.1	Navidea Biopharmaceuticals, Inc. press release dated May 15, 2013, entitled “Navidea Biopharmaceuticals Signs Manufacturing and Supply Agreement with Nordion.”

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 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, 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, Quarterly Reports on Form 10-Q, 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: May 16, 2013

By: /s/ Brent L. Larson

Brent L. Larson, Executive Vice President and
Chief Financial Officer

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

[¹²³I]NAV5001 Clinical Supply Agreement

THIS AGREEMENT made in duplicate as of this 10th day of May, 2013

BETWEEN:

Nordion (Canada) Inc.
having a place of business at
447 March Road
Ottawa, Ontario, Canada

(“Nordion”)

AND:

Navidea Biopharmaceuticals, Inc.
having a place of business at
425 Metro Place North, Suite 450
Dublin, OH 43017-1367, USA

(“Navidea”)

WHEREAS:

- I. Navidea is the licensee of a certain compound known as [¹²³I]NAV5001, an I-123 radiolabeled diagnostic agent;
- II. Navidea has the techniques and has demonstrated an ability to label a specific precursor molecule with I-123 to form [¹²³I]NAV5001;
- III. Nordion has expertise in the production of radiochemicals, and in the development of radiopharmaceuticals, processes, and radiolabelling of compounds;
- IV. Nordion has available for use a facility in Vancouver, British Columbia, suitable for the manufacture and supply of [¹²³I]NAV5001 to be used in Clinical Trials.
- V. Navidea desires that Nordion establish a development program at its site in Vancouver, British Columbia, for the purpose of radiolabelling Navidea’s Precursor with I-123 to form [¹²³I]NAV5001; and

VI. Navidea desires that Nordion manufacture and supply [¹²³I]NAV5001 for its Clinical Trials.

NOW THEREFORE in consideration of the mutual covenants and agreements herein contained, and subject to the terms and conditions hereinafter set out, the parties hereto agree as follows:

ARTICLE 1 – DEFINITIONS

For the purposes of this Agreement:

- 1.1 “**Affiliate**” shall mean an entity or person which controls, is controlled by or is under common control with either party. For purposes of this Section 1.1 control shall mean: (a) in the case of corporate entities, the direct or indirect ownership of more than one-half of the stock or participating shares entitled to vote for the election of directors; and (b) in the case of a partnership, the power to direct the management and policies of such partnership.
- 1.2 “**Batch**” shall mean a production batch of [¹²³I]NAV5001 manufactured under this Agreement in accordance to the Batch Sizes set out in Schedule D.
- 1.3 “**Batch Fee**” shall mean the price of each Batch as set out in Schedule D.
- 1.4 “**Scheduled Batch Production Date**” shall mean the production date on which Isotope is scheduled to be added to Precursor during the Manufacture of [¹²³I]NAV5001.
- 1.5 “**Clinical Trials**” shall mean human studies of [¹²³I]NAV5001 for the purpose of seeking pharmaceutical regulatory approval in Canada and United States.
- 1.6 “**Current Good Manufacturing Practices**” or “**cGMP(s)**” shall mean (1) the good manufacturing practices required by the FDA and as set forth in the FD&C or FDA rules and regulations for the manufacturing, testing and quality control of pharmaceutical materials as applied to compounds, as of the Effective Date of this Agreement and as may be supplemented, amended or modified from time to time; and (2) to the extent applicable to Nordion's activities hereunder, any rules, regulations and standards required by Health Canada for the manufacturing, testing and quality control of pharmaceutical materials as applied to compounds, as of the Effective Date of this Agreement and as may be supplemented, amended or modified from time to time.
- 1.7 “**Commercially Reasonable Efforts**” means, with respect to the efforts to be extended by a party with respect to any activity under this Agreement, exercising reasonable efforts, good faith and diligence in accordance with a party’s reasonable business judgment.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

- 1.8 “**Confidential Information**” means all non-public information disclosed, directly or indirectly, by one party to the other, whether disclosed orally, in writing or other tangible form, relating to technical or non-technical data, Nordion Background Technology, Navidea Background Technology, designs, drawings, know-how, formulas, policies, plan reports, trade secrets, processes, methods, product developments, material samples, business plans, forecasts, marketing plans, customer lists, business strategies and other documentation or information of a technical, financial or otherwise proprietary or confidential nature and such other information as clearly marked by the disclosing party as proprietary or confidential.
- 1.9 “**Data**” shall mean respectively, [¹²³I]NAV5001 and its predecessor product known as Altropane™ formulation data and data summaries, data reports, stability testing reports, production batch records, and validation reports generated under this Agreement and previously generated under the agreement between Nordion (Canada) Inc. (previously known as MDS Nordion Inc.) and [*] dated August 9, 2000, as amended. Data shall exclude Nordion Background Technology and Nordion Confidential Information.
- 1.10 “**Effective Date**” shall mean the date first appearing above.
- 1.11 “**Equipment**” means any equipment or machinery, and in the case of cGMP manufacturing hereunder, qualified equipment or machinery, used by Nordion in the development and/or Manufacture of [¹²³I]NAV5001 or the holding, processing, testing, or release of [¹²³I]NAV5001.
- 1.12 “**FDA**” shall mean the United States Food and Drug Administration.
- 1.13 “**FD&C**” shall mean the United States Federal Food, Drug and Cosmetic Act, as amended from time to time.
- 1.14 “**Facility**” shall mean the facility to be returned to operation by Nordion at its manufacturing site in Vancouver, British Columbia, as described in Schedule A, to be used for the production of [¹²³I]NAV5001.
- 1.15 “**Facility Milestone(s)**” shall mean the milestones relating to the return to operation of the Facility as described in Schedule A.
- 1.16 “**Facility Program**” shall mean the program by which Nordion shall return the Facility to operation in accordance with the Facility Milestones as described in Schedule A.
- 1.17 “**IND**” shall mean an Investigational New Drug Application as defined by the rules and regulations promulgated under the FD&C and related FDA rules and regulations as supplemented, modified or amended from time to time.

1.18 “**Isotope**” or “**I-123**” shall mean Iodine 123.

1.19 “**Manufacture (d) (ing)**” means any processes and activities necessary to produce [¹²³I]NAV5001, including without limitation, the processing, packaging, labeling, quality control testing, stability testing, release or storage of Precursor, Reference Standards and [¹²³I]NAV5001.

1.20 “**Master Batch Record**” or “**MBR**” shall mean a formal set of instructions for the Manufacture of each Batch developed and maintained in Nordion’s standard format by Nordion.

1.21 “**Master Validation Plan**” shall mean the program by which documented evidence provides assurance that the Process will consistently produce [¹²³I]NAV5001 that meets Specifications.

1.22 “[¹²³I]NAV5001” shall mean Navidea’s proprietary I-123 labeled diagnostic agent [*].

“NAV5001” shall mean [*].

“NAV5010” shall mean [*].

“NAV5011” shall mean [*].

1.23 “**NDA**” shall mean a new drug application seeking mandatory authorization in the United States as defined in the rules and regulations promulgated under the FD&C and related FDA rules and regulations, as supplemented, modified or amended from time to time.

1.24 “**Navidea Background Technology**” shall mean proprietary technology conceived, created, developed, reduced to practice, or acquired (by assignment, license or otherwise) by Navidea prior to or during the Term of this Agreement or independently of this Agreement, and independently of Nordion Background Technology including, without limitation, patents, works of authorship, know-how, concepts, ideas, techniques, methods, processes, drawings, schematics, procedures, protocols, parameters, engineering details, functional descriptions, data and database content, technical or scientific information, manuals and trade secrets, which Navidea owns, uses, conceives, creates, develops, reduces to practice or provides in performing under this Agreement, or which is licensed to Navidea which is in existence in the form of a writing, prototype or can otherwise be demonstrated to be the property of Navidea, or to which Navidea has the rights. For purposes of clarity, Navidea Background Technology shall include the Process to the extent contributed by Navidea and the Data and does not include Nordion Background Technology.

- 1.25 “**Nordion Background Technology**” shall mean proprietary technology, conceived, created, developed or reduced to practice, or acquired (by assignment, license or otherwise) by Nordion prior to or during the Term of the Agreement (except for the Process to the extent contributed by Navidea and Data) or independently of this Agreement, including, without limitation, patents, know-how, techniques, methods, processes, drawings, schematics, procedures, protocols, parameters, engineering details, functional descriptions, data and database content, technical or scientific information, manuals and trade secrets, which Nordion owns, uses, conceives, creates, develops, reduces to practice or provides in performing under this Agreement, or which is licensed to Nordion and which is in existence in the form of a writing, prototype or can otherwise be demonstrated to be the property of Nordion, or to which Nordion has the rights. For the purposes of clarity Nordion Background Technology does not include Navidea Background Technology.
- 1.26 “**Precursor**” shall mean NAV5010.
- 1.27 “**Process**” shall mean the method of producing [¹²³I]NAV5001 from the Precursor, including the radiolabelling of Precursor with I-123, as well as the formulation, dispensing and testing of [¹²³I]NAV5001 pursuant to this Agreement and previously generated under the agreement between Nordion (Canada) Inc. (previously known as MDS Nordion Inc. and [*] dated August 9, 2000, as amended.
- 1.28 “**Quality Agreement**” shall mean an agreement substantially in the form set out in Schedule E or as agreed upon by the parties subsequent to the execution of this Agreement.
- 1.29 “**Regulatory Authority**” shall mean Health Canada and the United States Food and Drug Administration.
- 1.30 “**Reference Standards**” shall mean NAV5001 and NAV5011.
- 1.31 “**Specification(s)**” shall mean those final conditions, characteristics and specifications for [¹²³I]NAV5001 as set out in Schedule B, as amended by mutual written agreement of the parties from time to time.
- 1.32 “**Term**” shall mean Term as defined in Section 17.1.

The following Schedules attached to this Agreement are hereby incorporated by reference:

Schedule A: Description of Facility Program, Milestones and Project Schedule

Schedule B: [¹²³I]NAV5001 Specifications

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Schedule C: Fees for Facility Program and Return to Operation of the Facility for Clinical Supply of [¹²³I]NAV5001

Schedule D: Price of Batches for Clinical Trials' Supply

Schedule E: Quality Agreement

Schedule F: Amounts and Specifications for Precursor and Reference Standards

Schedule G: Change in Scope Form

ARTICLE 2 – PURPOSE

2.1 Scope and Object

The scope and object of this Agreement is to prepare the Facility for the Manufacture of [¹²³I]NAV5001, refine the Process as necessary for the Manufacture of [¹²³I]NAV5001, and to subsequently Manufacture [¹²³I]NAV5001 for use in Clinical Trials.

ARTICLE 3 – FACILITY PROGRAM, AUDITS, MAINTENANCE

3.1 Facility Program

In consideration of the provision of services and activities carried out by Nordion in returning the Facility to operation, Navidea will pay to Nordion the fees as set out in Schedule C plus any applicable taxes. Unless otherwise set out, amounts owed by Navidea during the Facility Program shall be paid in accordance with Section 5.2.

Nordion shall establish the Facility in accordance with its obligations described and attributed in Schedule A, it being understood that some activities may be reasonably delayed to the extent that such activity is premised on the work or provision of data, information, Equipment or technology by Navidea and that some activities may be delayed if such activities materially interfere or could be reasonably expected to interfere with other established Nordion production activities. It is understood and acknowledged by Navidea that due to the nature of Nordion business and ongoing activities (including, without limitation, those activities carried on in rooms 112 A and 112 B at Nordion's site) there may be delays incurred in carrying out the obligations and achieving the milestones set out in this Agreement. Nordion will use Commercially Reasonable Efforts to minimize such delays and will keep Navidea advised of such situations during biweekly the calls or more often on an urgent basis as, and when, required.

Nordion recognizes the importance of the [¹²³I]NAV5001 program to Navidea and will place due and reasonable priority on the Facility Program work. Therefore, in carrying out the Facility Program Phase, Nordion will apply the necessary and appropriate resources in carrying out its obligations and activities set out in this Agreement.

Subject to the foregoing each party shall use their Commercially Reasonable Efforts in order to carry out their respective obligations and responsibilities set out in Schedule A in order to prevent or minimize delays in meeting Facility Milestones and each will keep the other advised of any situations which may result in such delays during biweekly calls or more often on an urgent basis as and when, required.

Nordion shall, in consultation with Navidea, develop and implement a Master Validation Plan that will allow the production of [¹²³I]NAV5001 under cGMPs for Clinical Trial supply. Prior to implementation, both parties shall in writing approve the Master Validation Plan, which approval will not be unreasonably or untimely withheld.

During the execution of the Facility Program Navidea will be called upon by Nordion to review and approve certain processes and documentation, as set forth in Schedule A. Nordion and Navidea agree that a reasonable time period for such reviews and receipt of feedback/approval is five (5) business days from the time Navidea receives the document and all other information reasonably necessary for such review. Navidea agrees that it will use Commercially Reasonable Efforts to effect such review and approval in the time period allotted. If the review by Navidea exceeds the time period allotted, such delay shall, at Nordion's option, require extension of the project schedule which will be effected through a scope change to reflect any delays and costs arising from such delay in the review.

3.2 Program Manager

The parties, upon signing this Agreement, shall each designate a program manager, who shall be responsible for coordinating communication and monitoring performance under this Agreement. The program manager for Nordion shall respond to Navidea's reasonable inquiries regarding the status of Nordion's activities under this Agreement and the Facility Program and shall keep Navidea informed as to interim progress. In addition, the program managers shall meet either bi-weekly or more frequently than bi-weekly if agreed to in advance by the parties, in person or by telephone, for the purpose of reviewing the status of the Facility Program and assessing progress against the milestones and activities set forth in Schedule A. Minutes of meetings shall be prepared, maintained and provided to each of the parties. Prior to the scheduled bi-weekly meetings, Nordion shall prepare and submit to Navidea the minutes from the previous meetings. Nordion will also inform Navidea in the biweekly calls in reasonable detail, the progress of the Facility Program and indicate any problems that are known to Nordion or reasonably anticipated by Nordion to occur that either may impact the project schedule for the Facility or may result in a scope change and cost increase to be borne by Navidea.

3.3 Scientific and Technical Dispute Resolution

In the event that at any time during the Term of this Agreement, a disagreement, dispute, controversy or claim should arise relating to scientific or technical issues in connection with Nordion's or Navidea's performance under this Agreement, the program managers will attempt, in good faith, to resolve their differences within a period of ten (10) business days (or less if the circumstances reasonably necessitate a faster resolution). With respect to such scientific or technical issues, if after ten (10) business days (or less if the circumstances reasonably necessitate a faster resolution) the program managers are unable to resolve such dispute, the program managers shall refer the matter to a joint steering committee comprised of at least three (3) senior members of each party who shall, in good faith, attempt to promptly resolve the matter. If the steering committee cannot resolve the matter, either party may seek any other remedy available. Notwithstanding the foregoing either party may take any action and seek any remedy it may have in law or equity without having fully complied with with the above dispute resolution process in order to avoid expiration of any applicable statute of limitations or as otherwise necessary to prevent irreparable harm.

3.4 Scope change

The parties acknowledge and agree that the project schedule and scope in Schedule A may require amendment during the course of establishing the Facility due to circumstances, issues or problems which the parties could not have reasonably foreseen in the exercise of commercially reasonable diligence. All such changes to Schedule A shall be made by written agreement of the parties in the form of a scope change (Schedule G). If any proposed change to Schedule A impacts the scope of work to be provided by Nordion such that Nordion will be required to provide (or procure) services, materials or Equipment beyond that agreed to in Schedule A, Nordion will provide Navidea a written quote of any increased cost and estimated delay, which must be approved by Navidea in advance of implementation. Any such approved changes in scope shall be charged to Navidea based on the quote provided by Nordion for the work set out in the scope change. No work on such scope change shall be carried out or implemented by Nordion prior to Nordion's receipt of Navidea's written approval of such change and appropriate scope change documentation being completed and signed by both parties.

3.5 Navidea Audits

During the Term of the agreement, upon ten (10) business days prior written notice to Nordion, Navidea and/or any third-party consultant or auditor appointed by Navidea, such consultant and/or auditor being subject to a confidentiality agreement with and reasonably acceptable to Nordion, shall have reasonable access to audit the Facility, the Process, as well as all applicable Process documents for the purpose of determining the progress against Facility Milestones and compliance with Schedules A and E. If Navidea elects to conduct more than (two) 2 calendar days of audit, per contract year, then such audits shall be treated as a scope change and the cost for such activities will be borne by Navidea in accordance with the rates set out in Schedule G. Notwithstanding the foregoing, should significant non-conformance by or attributable to Nordion be identified during an audit, Nordion will cooperate to resolve the non-conformance and Navidea will not be liable for Nordion costs incurred associated with such activities nor audit time required to confirm resolution of such matters.

ARTICLE 4 – MANUFACTURE AND PRICING

4.1 [¹²³I]NAV5001 Clinical Supply Readiness and [¹²³I]NAV5001 Clinical Manufacture

Nordion shall notify Navidea in writing of the completion of the Facility return to operation and readiness to Manufacture. After return to operation of the Facility, Nordion agrees to: (i) use the Process to Manufacture and produce Batches of [¹²³I]NAV5001 (in the Batch Sizes specified on Schedule D) solely for Navidea, and in such numbers as Navidea orders; and (ii) make arrangements for shipment of [¹²³I]NAV5001 to third parties on behalf of Navidea as directed by Navidea. All doses of [¹²³I]NAV5001 shall be shipped in regulatory approved lead shields. Nordion shall withhold from shipment any Batch, or portion thereof, which does not conform to the Specifications. All [¹²³I]NAV5001 Manufactured and delivered by Nordion hereunder (i) shall meet the Specifications and all applicable FDA requirements at the FCA (Incoterms 2010) point of delivery at Nordion's Facility ; and (ii) shall be Manufactured, and prepared for shipment in accordance with cGMPs, the Quality Agreement, and the Master Batch Record.

Subject to Section 4.6, Nordion shall ensure that the Facility is available for production runs of [¹²³I]NAV5001 at least once per week, on Wednesdays or on another day that the parties agree to in advance of any Scheduled Batch Production Date.

4.2 Clinical Trial Pricing

The purchase price for a Batch supplied to Navidea for Clinical Trials shall be as set out in Schedule D and shall be payable as set forth in Section 5.2 herein. All orders for [¹²³I]NAV5001 shall be forwarded by Navidea for receipt by Nordion at least seven (7) calendar days prior to the Scheduled Batch Production Date on which [¹²³I]NAV5001 is requested to be Manufactured.

4.3 Minimum Purchase Obligation

Commencing in the first full month after return to operation and readiness to Manufacture (as notified by Nordion to Navidea pursuant to Section 4.1), Navidea shall, during the remainder of the Term, purchase or otherwise pay Nordion for a minimum of [*]. In the event the minimum purchase obligations described in this Section 4.3 are not met by Navidea in any given month, Nordion may without liability, in addition to any other remedy available, at its sole option and unfettered discretion upon written notice to Navidea: (i) suspend Manufacture of [¹²³I]NAV5001 until full payment is made by Navidea (during which period the minimum purchase commitment shall continue to accrue); and/or (ii) terminate this Agreement upon ten (10) days prior written notice to Navidea. In the event that Nordion elects to suspend Manufacture of [¹²³I]NAV5001 due to Navidea's failure to meet its minimum purchase obligation pursuant to this Section 4.3 and Navidea subsequently cures such failure, Nordion agrees to resume Manufacture of [¹²³I]NAV5001 within fifteen (15) business days of such cure.

4.4 Facility Reservation Fees

If at any time during the Term of this Agreement and after Nordion has provided written notice of the Facility readiness to Manufacture [¹²³I]NAV5001 pursuant to Section 4.1, the use of the Facility is delayed or Manufacturing of [¹²³I]NAV5001 is temporarily or otherwise halted for reasons not attributable to Nordion's negligent acts or omissions, for a period of greater than or equal to three (3) consecutive months then, Navidea upon written notice thereof to Nordion, in lieu of the minimum purchase commitments set out in Section 4.3, shall pay to Nordion a facility reservation fee of [*], thereafter (or prorated portion thereof as applicable), which payment shall be due and payable on the first day of each month. The temporarily suspended minimum purchase commitment shall resume immediately upon resolution of the delay or halt preventing use of the Facility for the Manufacture of [¹²³I]NAV5001.

4.5 Batch Cancellation

Subject to the terms and conditions of this Agreement and subject to the minimum purchase commitment in Section 4.3, Navidea shall be entitled to cancel any Batch ordered from Nordion during the Term of this Agreement by providing to Nordion written notice of cancellation at least seven (7) calendar days prior to the Scheduled Batch Production Date. For a Batch cancelled by Navidea less than seven (7) calendar days prior to the Scheduled Batch Production Date, the entire purchase price of the Batch shall be payable by Navidea and the Batch payment shall be applied against the minimum purchase commitment in Section 4.3.

4.6 Use of the Facility

During the Term of this Agreement Nordion shall ensure that the Facility is available on a non-exclusive basis for the Manufacture of [¹²³I]NAV5001 for supply to Navidea. Nordion agrees that it shall not: (i) use other facilities for the Manufacture of [¹²³I]NAV5001 unless Navidea consents to the use of such other facilities in writing, such consent not to be unreasonably withheld; or (ii) Manufacture [¹²³I]NAV5001 for any third party unless directed to do so in writing by Navidea. Navidea acknowledges that the Facility is only suitable for Clinical Trial production and supply.

4.7 Repairs and Maintenance

After completion of the Facility Program, Nordion shall, subject to Section 14.7, maintain such Facility in satisfactory operating condition as required by the FDA, Specifications, Process, Quality Agreement and cGMPs. The cost of any repairs, preventive maintenance and service contracts for the Facility and Equipment shall be borne by Nordion. Navidea acknowledges that Nordion may periodically require the Facility to be unavailable for [¹²³I]NAV5001 production due to repair or unforeseen maintenance activities. In addition, Nordion may shut down the Facility annually for a two (2) week maintenance period. Such outages, to the extent possible in the circumstance, shall be subject to eight (8) weeks advance written notice to Navidea and, to the extent possible and reasonable in the circumstance, be planned in conjunction with Navidea so as to minimize the impact on Nordion’s supply capability of [¹²³I]NAV5001. Navidea’s obligations under Sections 4.3 and 4.4 shall not apply with respect to any Batch(es) that could not be produced during a period in which the Facility is unavailable for [¹²³I]NAV5001 production and in such event Navidea’s calendar month purchase commitment in such months shall be reduced as stated in the plan outlined in Table 1.

Table 1

If during any month or month(s) the Facility is unavailable for a period of	Then Navidea’s monthly minimum purchase commitment in such month or months will reduced by
Less than or equal to 1 week	[*]
More than 1 week and up to 2 weeks	[*]
Greater than 2 weeks	[*]

ARTICLE 5 –PRICE ESCALATION INVOICE AND PAYMENT

5.1 Price Escalation

During the Term of this Agreement the Batch Fee (Schedule D), scope change labour rates (Schedule G), those fees set out in Section 3.5 (audit activities), and facility reservation fees set out in Section 4.4, shall be subject to adjustment on each anniversary of the Effective Date in accordance with the change in the Canadian Consumer Price Index (“CPI”) as published by the Government of Canada. The CPI will be determined based on the percentage increase in the CPI for the twelve (12) month period ending with the calendar month which is three (3) months prior to each anniversary of the Effective Date.

5.2 Currency, Invoice and Payment

All sums expressed in this Agreement shall be in Canadian Currency unless otherwise specified.

Nordion shall invoice Navidea for the Facility Program, purchase price of Batches and such other amounts as are otherwise payable under this Agreement, plus all applicable taxes. Navidea shall be responsible for all services, sales, use, value added and similar taxes associated with the products and services provided by Nordion hereunder (specifically excluding taxes in the nature of ordinary personal property taxes assessed against or payable by Nordion, taxes based upon Nordion's net income, Nordion's corporate franchise taxes and the like). Nordion shall have the exclusive responsibility for remittance of all taxes payable and received from Navidea to the appropriate taxing authorities, and shall be exclusively liable for any penalties, interest and other charges of any jurisdiction and any other fees or costs arising from Nordion's failure to remit any such applicable taxes. Nordion's invoices hereunder shall separately itemize such taxes payable by Navidea.

All payments will be paid by Navidea within thirty (30) days of the date Navidea receives Nordion's invoice, as evidenced by an email, less any amounts disputed in good faith. Any undisputed amounts which remain unpaid after the aforementioned thirty (30) day period shall bear annual interest at the rate twelve percent (12%) annually and calculated at the rate of one percent (1%) monthly. Invoices dispatched by Nordion, shall be deemed received by Navidea as of the date of such email, as evidenced by the date appearing in the email sent by Nordion. Should Navidea fail to make payments on time on two or more consecutive occasions, Nordion may at its sole option, modify the future payment terms to require cash in advance of the Scheduled Batch Production date.

In the event Navidea disputes any particular invoiced item or amount, Navidea shall pay the non-disputed portion of the invoice and the parties shall attempt, in good faith, to resolve the dispute pertaining to the balance payable within fifteen (15) days of receipt of the notice of dispute issued by either party. In the event that the parties cannot resolve the dispute within the aforementioned fifteen (15) day period either party may pursue any remedy available under this Agreement or available at law. Navidea's election in good faith to withhold payment of any disputed amounts shall not excuse Nordion's obligation to perform under this Agreement.

ARTICLE 6 – PRECURSOR AND REFERENCE STANDARDS

6.1 Precursor and Reference Standards

Navidea, or at Navidea's discretion, its designee, shall provide to Nordion, at no charge, Precursor and Reference Standards which meet the specifications in Schedule F in sufficient quantities to permit Nordion to meet its obligations hereunder including but not limited to those obligations with respect to development, validation runs and Clinical Trials' supply. Nordion shall only use Precursor and Reference Standards provided hereunder for the Manufacture of [¹²³I]NAV5001 pursuant to this Agreement. Nordion shall store Precursor and Reference Standards in accordance with the written instructions provided by Navidea.

6.2 Unavailability or Scarcity of Precursor and/or Reference Standards

After issuance of the notice of completion of the Facility and return to operation pursuant to section 4.1, Nordion, on a monthly basis, will provide Navidea with a detailed physical inventory status of NAV5001, NAV5010, and NAV5011 that is available to Manufacture Batches. Navidea will notify Nordion in writing upon Navidea becoming aware of any shortage or delay of supply of Precursor or Reference Standards if such shortage or delay will impact the manufacture of [¹²³I]NAV5001. Navidea shall be responsible for any failure of Precursor or Reference Standards to meet the applicable specifications (Schedule F) and any such shortages, delay or failure to meet specification which is not attributable to any act, failure to act or other fault of Nordion or Force Majeure, will not relieve Navidea of its payment obligations pursuant to Section 4.3, Section 4.4 and Section 4.5 and shall excuse Nordion's performance of activities related to any affected Batch of [¹²³I]NAV5001 or scheduled Batch production to the extent that Nordion's non-performance was caused by the Precursor or Reference Standards supply delay or shortage. To the extent that any Precursor or Reference Standards supply delays or shortages are attributable to the improper storage or handling of Precursor or Reference Standards by Nordion, or are attributable to any other act, failure to act or other fault of Nordion, Navidea shall be relieved of its obligations with respect to affected batches pursuant to Sections 4.3 and 4.4 during the period of any such shortages or delays.

6.3 Compliance with Law and Handling

While Precursor, Reference Standards, Isotope and [¹²³I]NAV5001 are in its possession or under its control, Nordion shall be responsible for compliance in all material respects with applicable laws, rules and regulations in the United States and Canada related to its possession of such Precursor, Reference Standards, Isotope and [¹²³I]NAV5001. Navidea shall be responsible for compliance in all material respects with all applicable laws, rules and regulations relating to its obligations under this Agreement, including but not limited with respect to the Precursor, Reference Standards, [¹²³I]NAV5001, its Clinical Trials, IND and NDA.

ARTICLE 7 – [¹²³I]NAV5001 SHIPMENTS

7.1 Orders and Shipments

Navidea will forward orders to Nordion's Customer Service team at its Ottawa, Ontario facility, and Nordion shall promptly acknowledge receipt of every order, by facsimile, email or such other method as agreed by the parties in writing. Each order will reference this Agreement and set forth the quantity of [¹²³I]NAV5001 to be produced and prepared for shipment, the identity of the recipients, delivery destination protocol numbers, IND/NDA number, applicable USNRC materials license number and IRS number. Delivery of [¹²³I]NAV5001 to Navidea or as otherwise directed by Navidea shall be FCA (Incoterms 2010) at the Facility. Risk of loss of [¹²³I]NAV5001 shall pass to Navidea at the point of shipment FCA (Incoterms 2010) Nordion's Facility. The standard terms and conditions on the reverse side or attached to Navidea's purchase orders shall not apply and shall be deemed objected to by Nordion, and of no application.

Nordion shall use Commercially Reasonable Efforts to meet Navidea's orders and delivery requirements. Prior to the first shipment of [¹²³I]NAV5001 to any third party site, Navidea shall obtain from such third party and provide to Nordion such third party's license evidencing proper legal authority for the receipt and possession of [¹²³I]NAV5001 by such third party. Nordion shall be responsible for compliance with all export formalities necessary for, and the payment of all export duties, taxes and other charges payable upon, the export of [¹²³I]NAV5001 from Canada, including obtaining at its risk and expense any export license or other official authorization or other documents necessary therefor. Navidea shall be responsible for compliance with all import formalities necessary for, and the payment of all import duties, taxes and other charges payable upon, the importation of [¹²³I]NAV5001 into the United States, including obtaining at its risk and expense any import license or other official authorization or other documents necessary therefor. Nordion shall make shipping arrangements and will coordinate with FedEx or such other carrier designated by Nordion and reasonably approved by Navidea. All [¹²³I]NAV5001 shipping costs incurred from the FCA (Incoterms 2010) point of delivery shall be borne by Navidea.

ARTICLE 8 – PRODUCT WARRANTY AND LIMITED LIABILITY

8.1 Product Warranty

Nordion provides a product warranty such that each Batch: (i) will conform with the Specifications and all applicable FDA requirements at the FCA (Incoterms 2010) point of delivery ; and (ii) will be free from defects in material or workmanship and be Manufactured, and prepared for shipment in accordance with cGMPs, the Master Batch Record, and the Quality Agreement. Nordion further warrants that the [¹²³I]NAV5001 packaging will conform to all applicable packaging regulations, including, but not limited to, those pertaining to packaging and transport of radioactive materials and radiopharmaceutical products.

Navidea will notify Nordion if Navidea becomes aware of any alleged visible defects, damages or shortage at the time of delivery of [¹²³I]NAV5001 hereunder. However, a failure to so notify shall not negate any of Nordion's warranties, liabilities, indemnifications or other obligations set forth herein except to the extent such failure of Navidea to notify results in material prejudice to Nordion. All warranty obligations of Nordion shall cease and have no effect if the NAV5001 is subject to accident, abuse, misuse, combination, alteration, neglect or not used or stored by Navidea or its third party, customer, or user, in accordance with the specifications or package insert. If requested by Nordion, defective product must be held for Nordion's inspection or returned at Nordion's expense.

If either party discovers or learns, at any time, that a Batch, including any portion thereof, does not meet the Specifications, was not Manufactured in accordance with cGMPs, the Master Batch Record or the Quality Agreement, or is mislabeled, adulterated or otherwise defective, then that party shall promptly communicate with the other party. Without limiting any other rights and remedies Navidea may have under this Agreement, if Navidea determines that the failure to meet Specifications, failure to Manufacture in accordance with cGMPs, the Master Batch Record or the Quality Agreement, or any other defect is the result of a negligent act, failure to act or other fault of Nordion, or agent of Nordion, Nordion will promptly:

- (i) replace such Batch, at no additional cost to Navidea; and
- (ii) pay for shipping costs of replacement of such Batch.

In the event that Nordion disputes, in good faith, Navidea's determination that the fault is due to Nordion and/or its agent, the parties will select a mutually acceptable outside consulting firm which will be instructed to review the applicable information and data and confirm or dissent from Navidea's determination. If the consulting firm confirms Navidea's determination, Nordion will have the obligations set out in this Section and Nordion will pay the fees of such consulting firm. If the consulting firm dissents from Navidea's determination or determines that the failure to meet Specifications was due to products, information or services supplied by Navidea, Nordion will not have the obligations set out in this Section with respect to the disputed Batch and Navidea will pay for such Batch, return shipping costs and the fees incurred for such consulting firm.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

8.2 Acknowledgement

NAVIDEA ACKNOWLEDGES THAT NORDION IS MANUFACTURING AND SUPPLYING PRODUCT TO MEET SPECIFICATIONS. EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT, NORDION HEREBY DISCLAIMS ALL OTHER WARRANTIES OR CONDITIONS, WHETHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OR CONDITIONS OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, USE OR APPLICATION.

8.3 Disclaimer

NORDION'S LIABILITY TO NAVIDEA FOR DAMAGES HOWSOEVER CAUSED SHALL NOT EXCEED PAYMENT ACTUALLY RECEIVED BY NORDION FOR THE PRODUCT OR SERVICES FURNISHED HEREUNDER AND EXCEPT IN THE CASE OF THEIR RESPECTIVE INDEMNIFICATION OBLIGATIONS HEREIN, BREACH OF CONFIDENTIALITY, MISAPPROPRIATION OF THE INTELLECTUAL PROPERTY RIGHTS OF THE OTHER PARTY, WILLFUL MISCONDUCT, OR GROSS NEGLIGENCE, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR INDIRECT, CONTINGENT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BREACH OF STATUTORY DUTY OR ANY OTHER CAUSE OF ACTION, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 9 – NONCOMPETE

9.1 During the Term of this Agreement, Nordion will not produce for, or sell or provide to, any third party [¹²³I]NAV5001 except as instructed by Navidea. For the purpose of certainty, Nordion shall not be restricted in any way from developing, producing or selling I-123 radiochemical or any other I-123 radiopharmaceutical product or selling any other product for use in the treatment or diagnosis of Parkinson's disease, provided that Nordion shall not use any Navidea Background Technology, the Process to the extent contributed by Navidea, the Data, Confidential Information disclosed or provided by Navidea, or any other intellectual property of Navidea except for the sole purpose of satisfying its obligations under this Agreement.

ARTICLE 10 – LICENSE/OWNERSHIP

10.1 Royalty-Free License

Navidea hereby provides to Nordion a non-exclusive, nontransferable (except in connection with the sale of all or substantially all of the assets of Nordion or business to which this Agreement relates to a third party or in connection with a merger consolidation or similar transaction involving Nordion), non-sublicensable, fully paid-up, royalty-free, worldwide license during the Term of this Agreement to use Navidea Background Technology, the Process to the extent contributed by Navidea, Data relating to [¹²³I]NAV5001 and the radiolabelling of Precursor with I-123, for the sole purpose of assisting Nordion in carrying out its obligations set out in this Agreement.

10.2 Technology Ownership

Navidea Background Technology shall remain the sole and exclusive property of Navidea (or its licensor, as applicable). Nordion Background Technology shall remain the sole and exclusive property of Nordion. The parties acknowledge and agree that to the extent that the Process is jointly developed by Nordion and Navidea during the Term of this Agreement then each party may continue to use and exploit such jointly developed technology as their own technology both during and after the Term of this Agreement.

Nothing in this Agreement permits the use, transfer or license of any right, title or interest to Navidea Background Technology or Nordion Background Technology, except as expressly set out herein.

10.3 Ownership of Physical Assets, Precursor, Reference Standards and Data

At all times (both during the Term and after expiration or termination of this Agreement for any reason) Nordion will retain all right and title in and to the physical assets and real property that comprise and/or are used and/or employed in the Facility.

Navidea shall at all times (both during the Term and after expiration or termination of this Agreement for any reason) retain title to and ownership of Precursor, Reference Standards, Process to the extent contributed by Navidea and Data, provided further, that both during the Term and after termination and/or expiration of this Agreement: (i) Nordion may retain an archival copy of the Data for the purpose of management of its obligations under this Agreement; (ii) Nordion may use the Data for regulatory purposes with respect to [¹²³I]NAV5001; and (iii) Nordion may use the Data internally, and without disclosing the Data to any third party, for the purpose of increasing its general knowledge and experience with respect to its radiopharmaceutical capabilities. Nordion will not use Data in any regulatory submission to any national regulatory authority for the purpose of clinical investigation or licensure of any Nordion produced [¹²³I]NAV5001 dose form. During the Term of this Agreement, Nordion shall take all such measures as are required to properly and adequately store the Precursor, Reference Standards, and [¹²³I]NAV5001 in accordance with applicable specifications, the Master Batch Record, laws and regulations. Nordion shall immediately notify Navidea if at any time it believes any Precursor, Reference Standards and/or [¹²³I]NAV5001 has been damaged, lost, or stolen.

ARTICLE 11 – NAVIDEA’S REPRESENTATIONS AND WARRANTIES

11.1 Navidea’s Representations and Warranties

Navidea represents and warrants that:

- (i) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;
- (ii) it has full right, power and authority to enter into this Agreement;

it is the owner or has the right to use the Navidea Background Technology, and Process (to the extent provided by Navidea) supplied to Nordion by Navidea to assist Nordion in the Manufacture of [¹²³I]NAV5001 and in carrying out its obligations hereunder;
- (iii) to Navidea’s knowledge, there is no action or proceeding pending or, to its knowledge, threatened against Navidea or its licensor with respect to Navidea Background Technology before any court, administrative agency or other tribunal which would have an adverse material effect on its ability to perform its obligations hereunder;
- (iv) it has the right to grant the license in Section 10.1 and it is the owner or otherwise has the right by license or otherwise (and is not in default thereunder) to permit Nordion to use Navidea Background Technology required to assist and enable Nordion to carry out its Manufacturing obligations under this Agreement;
- (v) it has not received any written notice of adverse claim or infringement of any patent or other intellectual property right, or of misappropriation of trade secrets, in connection with the use and exploitation of Navidea Background Technology related to its activities under this Agreement or the use and exploitation of the Precursor, Reference Standards or [¹²³I]NAV5001 or its intended application;
- (vi)

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

- (vii) to Navidea’s knowledge, Manufacturing, using, offering for sale or selling of Precursor, Reference Standards and [¹²³I]NAV5001, and the Navidea Background Technology (and the Process to the extent provided by Navidea) do not infringe any valid third party patent or other intellectual property right of any third party;
- (viii) it is not under any obligations, contractual or otherwise, to any other entity that might conflict, interfere or be inconsistent with the execution, delivery or any of the provisions of this Agreement;
- (ix) it shall obtain and at all times during the Term of this Agreement maintain at its expense, all licenses, permits and approvals necessary for it to perform its obligations under this Agreement;
- (x) it is not currently subject to any proceeding which is pending or, to its knowledge, threatened, for reorganization, liquidation or dissolution for the benefit of its creditors or otherwise;
- (xi) [¹²³I]NAV5001 shall not be misbranded within the meaning of the FD&C as a result of the proper application of the label content supplied by Navidea to Nordion pursuant to this Agreement, and [¹²³I]NAV5001 is not an article which may not be introduced into interstate commerce under the provisions of section 505 of the FD&C.

ARTICLE 12 – NORDION’S REPRESENTATIONS AND WARRANTIES

12.1 Representations and Warranties

Nordion represents and warrants that:

- (i) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;
- (ii) it has full right and authority to enter into this Agreement;
- (iii) it is the owner or has the right to use the Nordion Background Technology and other Nordion proprietary technology to be used, or necessary for Nordion to perform its obligations under this Agreement, during the Term of this Agreement;
- (iv) to Nordion's knowledge, Manufacturing [¹²³I]NAV5001 and the Nordion Background Technology used in carrying out its activities under this Agreement do not infringe any valid third party patent or other intellectual property right of any third party;

- (v) it has not received any notice of adverse claim or infringement of any patent or other intellectual property right, or of misappropriation of trade secrets, in connection with the use and exploitation of the Nordion Background Technology related to its activities under this Agreement;
- (vi) there is no action or proceeding pending or, to its knowledge, threatened against Nordion before any court, administrative agency or other tribunal which would have an adverse material effect on Nordion's ability to perform its obligations hereunder;
- (vii) Nordion is not currently subject to any proceeding which is pending or, to its knowledge, threatened, for reorganization, liquidation or dissolution for the benefit of its creditors or otherwise;
- (viii) it shall obtain and at all times during the Term of this Agreement maintain, at its expense, all licenses, permits and approvals necessary for it to carry out its activities and obligations under this Agreement;
- (ix) it is not under any obligations, contractual or otherwise, to any other entity that might conflict, interfere or be inconsistent with the execution, delivery or any of the provisions of this Agreement;
- (x) [¹²³I]NAV5001 delivered pursuant to this Agreement shall, at the time of delivery by Nordion to Navidea, not be misbranded (to the extent branded by Nordion) or adulterated within the meaning of FD&C.

ARTICLE 13 – INDEMNITY

13.1 Indemnification by Navidea

Navidea agrees to indemnify, defend and hold Nordion and its Affiliates and their respective directors, officers, employees and agents, representatives, successors, heirs and permitted assigns harmless from and against any damages, claims, liabilities and expenses (including, but not limited to, reasonable attorney's fees) resulting from any third party claims or suits ("**General Claims Against Nordion**") to the extent arising out of: (a) Navidea's or a third party's use, handling or shipping of Reference Standards, Precursor or [¹²³I]NAV5001 (including in the event that Nordion makes shipping arrangements on behalf of Navidea); (b) Navidea's breach of any of its obligations, warranties or representations hereunder; (c) Navidea's, its subcontractors', agents' or employees' negligent acts or omissions or willful misconduct; or (d) failure of the Reference Standards or Precursor to meet applicable specifications. Notwithstanding anything in this Section 13.1, "General Claims Against Nordion" shall not include "IP Claims Against Nordion" as described in Section 13.3.

13.2 Indemnification by Nordion

Nordion agrees to indemnify, defend and hold Navidea and its Affiliates and their respective directors, officers, employees and agents, representatives, successors, heirs and permitted assigns harmless from and against any damages, claims, liabilities and expenses (including, but not limited to, reasonable attorney's fees) resulting from any third party claims or suits ("**General Claims Against Navidea**") to the extent arising out of: (a) Nordion's Manufacture (except to the extent arising out of any portion of the Process, labels and/or content thereof which was provided by Navidea) or preparation for shipment of [¹²³I]NAV5001; (b) Nordion's breach of any of its obligations, warranties or representations hereunder; (c) Nordion's, its subcontractors', agents' or employees' negligent acts or omissions or willful misconduct; or (d) any failure of the [¹²³I]NAV5001 to meet the Specifications. Notwithstanding anything in this Section 13.2, "General Claims Against Navidea" shall not include "IP Claims Against Navidea" as described in Section 13.4.

13.3 Intellectual Property Claims Against Nordion

Navidea agrees to indemnify, defend and hold Nordion and its Affiliates and their respective directors, officers, employees, agents, representatives, successors, heirs and permitted assigns harmless from and against any damages, claims, liabilities and expenses (including, but not limited to, reasonable attorneys' fees) resulting from any third party claims or suits arising out of any proceeding instituted by or on behalf of a third party based upon a claim that Navidea Background Technology, the Process (to the extent contributed by Navidea), or the use or sale of the Reference Standards, Precursors or [¹²³I]NAV5001 infringes a patent or any other intellectual property right of a third party ("**IP Claim Against Nordion**").

13.4 Intellectual Property Claims Against Navidea

Nordion agrees to indemnify, defend and hold Navidea and its Affiliates, and their respective directors, officers, employees, agents, representatives, successors, heirs and permitted assigns harmless from and against any damages, claims, liabilities and expenses (including, but not limited to, reasonable attorney's fees) resulting from any third party claims or suits arising out of any proceeding instituted by or on behalf of a third party based upon a claim that the Nordion Background Technology, the method of Manufacture of [¹²³I]NAV5001, or the Process (to the extent developed or contributed by Nordion) infringes a patent or any other intellectual property right of a third party ("**IP Claim Against Navidea**").

13.5 Obligations of Nordion With Respect to Infringement Claims

In the event that any portion of the Nordion Background Technology, required in the Manufacture of [¹²³I]NAV5001, in the opinion of independent counsel mutually selected by the parties, becomes the subject of a valid claim for a patent, copyright or other intellectual property right infringement then Nordion shall for a period of at least sixty (60) days after issuance of the opinion, use its Commercially Reasonable Efforts to:

- i) procure the right to continue using the technology or method of Manufacture,
- ii) modify the Nordion Background Technology, method of Manufacture to become non-infringing (with all Nordion costs, including any commercially reasonable increase to the cost of the manufacturing of [¹²³I]NAV5001 to be borne by Nordion)
- iii) obtain an opinion of independent counsel mutually selected by the parties that the claim or allegation of infringement is not valid.

If Nordion is unable to resolve the claim or allegation of infringement on commercially reasonable terms in accordance with subparagraph i), ii) or iii) above within 90 days, Navidea or Nordion, may upon written notice, suspend the Manufacture of [¹²³I]NAV5001 and/or terminate this Agreement. The provisions of this Section 13.5 are in addition to, and do not in any way limit, the indemnification obligations of Nordion set forth in this Article 13.

13.6 Obligations of Navidea With Respect to Infringement Claims

In the event [¹²³I]NAV5001, that any portion of the Navidea Background Technology required in the Manufacture of [¹²³I]NAV5001, in the opinion of independent counsel mutually selected by the parties or the Process (to the extent contributed by Navidea), becomes the subject of a valid claim for a patent, copyright or other intellectual property right infringement, then Navidea shall for a period of at least sixty (60) days after issuance of the opinion, use its Commercially Reasonable Efforts to:

- i) procure the right to continue using the technology,
- ii) modify the Navidea Background Technology to become non-infringing provided such modification does not increase the cost of Manufacture of [¹²³I]NAV5001 by Nordion (with all Navidea's costs including any increase to the cost of the Manufacture of [¹²³I]NAV5001 by Nordion to be borne by Navidea)
- iii) obtain an opinion of independent counsel mutually selected by the parties that the claim or allegation of infringement is not valid.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

If Navidea is unable to resolve the claim or allegation of infringement on commercially reasonable terms in accordance with subparagraph i), ii) or iii) above within 90 days, Nordion or Navidea may upon written notice, suspend Manufacture activities and/or terminate this Agreement. The provisions of this Section 13.6 are in addition to, and do not in any way limit, the indemnification obligations of Navidea set forth in this Article 13.

13.7 **Indemnification Procedures**

A party (the “**Indemnitee**”) intending to claim indemnification under this Agreement shall promptly notify the other party (the “**Indemnitor**”) in writing of any action, claim or other matter in respect of which the Indemnitee or any of its directors, officers, employees or agents intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is materially prejudiced by such failure. The Indemnitor shall be entitled to control the defense of and/or settle any such action, claim or other matter. The Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor, provided, however, any settlement of such claims shall require the Indemnitee’s prior written consent unless such settlement includes a full release of the Indemnitee, in which case no consent shall be required. The Indemnitee and its directors, officers, employees and agents shall co-operate fully with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

ARTICLE 14 – REGULATORY MATTERS

14.1 **Navidea Responsibilities**

It shall be the responsibility of Navidea or its designee to file, obtain and maintain an IND/NDA, registrations, listings, authorizations and approvals as the FDA or any other applicable governmental entity may require to enable use of [¹²³I]NAV5001 in Clinical Trials in the United States and Canada. Navidea will be responsible for any FDA and Health Canada fees specifically related to Clinical Trials of [¹²³I]NAV5001. Nordion shall provide directly to Navidea, or at Nordion’s discretion for the purpose of protection of its proprietary technology with respect to the manufacture of the Isotope, directly to the regulatory authority (with a copy to Navidea purged of Nordion proprietary technology) all required information in its possession necessary to assist Navidea in filing, obtaining and maintaining all licenses, registrations, listings, authorizations and approvals of any governmental entities necessary for the use of [¹²³I]NAV5001 in support of Navidea’s [¹²³I]NAV5001 IND/NDA submission. Navidea will provide Nordion with copies of any submissions made describing activities that occur at Nordion.

14.2 Nordion Responsibilities

Nordion shall be responsible for obtaining and maintaining, at its sole expense, all necessary facility licenses, registrations, authorizations and approvals which are necessary to Manufacture, prepare for shipment, and export [¹²³I]NAV5001 in accordance with cGMPs, the Master Batch Record and the Quality Agreement and other regulatory requirements including, but not limited to, the use and handling of radioactive materials.

At Nordion's expense, Nordion shall update and maintain its existing I-123 bulk chemical Drug Master File (“DMF”) with the FDA as may be required for Navidea's IND/NDA for [¹²³I]NAV5001. Nordion hereby grants Navidea for the purpose of this Agreement, a right of reference to such DMF and upon request shall provide a letter of access to the DMF allowing regulatory review of the DMF by the FDA in conjunction with Navidea's [¹²³I]NAV5001 submissions.

14.3 Government Inspections, Compliance Review and Inquiries

Upon request of any governmental entity or any third party entity authorized by a governmental entity, such entity shall, for the purpose of regulatory review and compliance, have access to observe and inspect the: (i) Facility; (ii) procedures used for the storage of Reference Standards and Precursor; and (iii) manufacturing, testing, storage and preparation for shipment of [¹²³I]NAV5001, including Process development operations, and auditing the Facility for compliance with cGMP and/or other applicable regulatory standards. Nordion shall give Navidea prompt written notice of any upcoming inspections or audits by a governmental entity of the Facility or any of the foregoing, shall allow Navidea to participate in such inspections by being present at any such FDA close-out meetings and shall provide Navidea with a written summary of such inspection within five (5) business days following completion thereof. Nordion agrees to use Commercially Reasonable Efforts to promptly rectify or resolve any deficiencies noted by a government entity in a report or correspondence issued to Nordion or Navidea. Subject to any specific arrangements agreed upon by the parties, Navidea shall be responsible for communicating with any governmental authority concerning [¹²³I]NAV5001 or the marketing, distribution, sale or clinical use of [¹²³I]NAV5001, and Nordion shall, in accordance with the compensation rates set forth in Section 3.5 provide Navidea with whatever assistance Navidea may reasonably require to assist it in such communications. Nordion shall have no such communications specifically related to [¹²³I]NAV5001, except to the extent (and notwithstanding its confidentiality undertakings in this Agreement) that they relate to Nordion's Manufacture of [¹²³I]NAV5001 under this Agreement or as required of Nordion directly by the governmental or regulatory authority, in which case Nordion shall be responsible for such communications. Notwithstanding the foregoing and except to the extent that an immediate or urgent communication is necessary under the circumstances or required by law, Nordion in good faith shall consult in advance with Navidea regarding all communications that relate to [¹²³I]NAV5001 or to Nordion's ability to Manufacture [¹²³I]NAV5001 pursuant to this Agreement.

14.4 Complaints and Adverse Events

Nordion and Navidea shall fully comply with the terms of the Quality Agreement regarding their respective obligations and responsibilities with respect to any complaints or adverse events regarding the Precursor, Reference Standards, [¹²³I]NAV5001, Isotope, and other activities related to this Agreement.

14.5 Recalls

Nordion and Navidea shall fully comply with the terms of the Quality Agreement regarding their respective obligations and responsibilities with respect to any recall of or corrective action related to the Precursor, Reference Standards or [¹²³I]NAV5001. Navidea shall notify Nordion promptly if [¹²³I]NAV5001 is the subject of a recall or correction (a “**Recall**”), and Navidea and/or its designee shall have sole responsibility for the handling and disposition of such Recall. Navidea and/or its designee shall bear the costs of any Recall of [¹²³I]NAV5001 unless and to the extent such Recall shall have been the result of Nordion’s or its agents or employees negligent acts or omissions or any product defects for which Nordion is responsible in which case Nordion shall to such extent be responsible for all of Navidea’s reasonable out-of-pocket costs incurred for:

- (i) notification of recall to Nordion and third parties;
- (ii) return shipment or destruction of any defective [¹²³I]NAV5001 to Nordion; and
- (iii) replacement of [¹²³I]NAV5001 .

In the event that Nordion disputes Navidea’s determination that the fault is due to Nordion and/or to its employees or agents, the parties will select a mutually agreeable outside consulting firm which will be instructed to review the applicable information and data and to confirm or dissent from Navidea’s determination. If the consulting firm confirms Navidea’s determination, Nordion will pay the fees of such consulting firm. If the consulting firm dissents from Navidea’s determination Nordion will not have the obligations set forth herein with respect to the Recall and Navidea will pay the fees of such consulting firm. Navidea and/or its designee shall maintain records of all sales, shipping records of [¹²³I]NAV5001 and customers in sufficient detail to adequately administer a Recall for the period of time as required by applicable regulation.

14.6 New Regulatory Requirements

Each party shall promptly notify the other of new regulatory requirements of which it becomes aware which are relevant to the manufacture of NAV5001 under this Agreement and which are required by the FDA and other applicable governmental entities. The parties shall confer with each other with respect to the best means to implement and comply with such requirements.

If after the Effective Date any Facility investment above [*] in aggregate is required during any calendar year to comply with any new regulatory requirement or cGMP mandated by applicable law or a Regulatory Authority, such investment in excess of [*] shall be treated as a scope change pursuant to Section 3.4 (Schedule G) and paid for by Navidea.

14.7 Records

Nordion shall maintain, and provide Navidea reasonable access to, all records, both during and after the termination or expiration of this Agreement, in accordance with the Quality Agreement. The cost of any off-site storage of such records after the Term of this Agreement shall be borne by Navidea and invoiced on a calendar quarter basis. In the event that Navidea fails to cover the cost of storage after the Term of the Agreement then Nordion may offer to ship the records to Navidea at Navidea's cost and if Navidea fails to pay such costs or declines to receive such records, Nordion, in addition to any other remedy available, shall have the right to dispose of such records as it sees fit.

14.8 Labels

Navidea shall be solely responsible for, and shall provide and approve the form and content of, the labels (except lot number and expiry date which shall be the responsibility of Nordion) to be applied to [¹²³I]NAV5001. Label form and content (other than lot number and expiry date) shall remain the liability and exclusive property of Navidea. Such labels shall not be used by Nordion after termination or expiration of this Agreement and the label provided by Navidea may only be used by Nordion for the purpose of performing its obligations under this Agreement.

14.9 Testing, Documentation, and Quality Assurance

Nordion shall maintain, and provide Navidea reasonable access to, accurate and complete production records with respect to the Process, Batches and shipments in accordance with the Quality Agreement.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

The parties agree to execute, and shall comply with their respective obligations and duties set forth in, the Quality Agreement in substantially the form attached as Schedule “E”.

ARTICLE 15 – CONFIDENTIALITY

15.1 Confidentiality and Exceptions

During the Term of this Agreement and thereafter, each party hereto shall maintain in confidence the other party’s Confidential Information and will not use such information or disclose the content of the transactions contemplated herein to third parties for any purpose other than to its employees, agents or consultants (which agents or consultants will be bound by a confidentiality agreement incorporating no less restrictive terms than those set forth herein or that are otherwise reasonably accepted in writing by the other party) with a need to know such information to perform such party’s obligations under this Agreement as expressly authorized in this Agreement. This obligation of confidentiality shall not apply to the extent that it can be established by the party in receipt of such information, that the information:

- (i) was already known to the receiving party at the time of disclosure as evidenced by written records that existed prior to the party’s receipt of such information;
- (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure to the receiving party through no act or omission of the receiving party;
- (iv) was lawfully disclosed to the receiving party by a third party who was not bound to obligations restricting disclosure of such information; or
- (v) was independently developed by the receiving party without any use of Confidential Information of the disclosing party, in whole or in part, as evidenced by written records that existed prior to the party’s receipt of such information.

Each party agrees that it will take the same degree of care to protect the confidentiality of the other party’s Confidential Information as it takes to protect its own proprietary and confidential information, which shall in no event be less than a reasonable degree of care. Each party, and its employees and agents shall protect and keep confidential and shall not use, publish or otherwise disclose to any third party, except as permitted by this Agreement, or with the other party’s written consent, the other party’s Confidential Information.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

All Confidential Information supplied by one party to the other to assist in carrying out the obligations hereunder shall remain the property of such party and shall be returned to the other party upon termination or expiration of this Agreement.

ARTICLE 16 – DISCLOSURE OF INFORMATION

16.1 Authorized Disclosure

Notwithstanding Section 15.1 each party may disclose Confidential Information to the extent such disclosure is necessary for prosecuting or defending litigation and/or complying with applicable government laws, rules or regulations, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information, except where impracticable for necessary disclosure, for example in the event of medical emergency, it will give reasonable notice to the other party of such disclosure requirement prior to making the disclosure. Such prior notice shall be in a form sufficient to allow the other party a reasonable opportunity to contest or limit any such disclosure. In the event that Confidential Information is required to be disclosed by Navidea or Nordion pursuant to any applicable law or requirement of a federal, provincial, state or foreign authority, court or administrative or regulatory body, Navidea or Nordion, as the case may be, shall provide reasonable notice to the other prior to any such disclosure (and as permitted by applicable law) in order that such party may seek a protective order to preserve the confidentiality of the Confidential Information prior to its disclosure. The party being required to disclose shall only disclose such portions of Confidential Information as are strictly required to be disclosed the applicable law or requirement of a federal, provincial, state or foreign authority, court or administrative or regulatory body, and if permitted by applicable law the other party shall be provided with the opportunity to review and comment on the disclosure to be made. The party being required to disclose shall not be prevented from complying with the applicable requirement if the other party does not seek or obtain a protective order or does not provide its comments on the disclosure promptly.

ARTICLE 17 – TERM AND TERMINATION

17.1 Term

This Agreement shall commence upon the Effective Date and, unless terminated earlier pursuant to this Agreement or extended upon mutual agreement of the parties, shall expire three (3) years after the Effective Date.

17.2 Termination Without Cause by Navidea

Navidea may terminate this Agreement without cause or penalty upon one hundred and eighty (180) days prior written notice to Nordion. Upon such termination, Nordion will be entitled to retain all amounts paid by Navidea, and Navidea shall pay to Nordion any undisputed, unpaid amounts due or earned by Nordion. In the event of such termination without cause by Navidea, for the purpose of clarity Nordion's obligations and Navidea's obligations under this Agreement (including but not limited to Sections 4.3 and 4.4) shall continue to apply during the notice period.

17.3 Termination for Breach

This Agreement may be terminated by a party in the event of breach by the other party of a material term or condition hereof, provided however, the other party shall first give to the breaching party written notice of the proposed termination of this Agreement (a "**Breach Notice**"), specifying the grounds therefore. Upon receipt of such Breach Notice, the breaching party shall have such time as necessary, but in any event not more than thirty (30) days to cure such breach or fifteen (15) days with respect to a failure by Navidea to pay any amounts hereunder when due other than with respect to unpaid amounts which Navidea, in good faith, disputes are due to Nordion. Notwithstanding the foregoing, if the breaching party does not cure such breach within such cure period, the other party may, upon written notice, terminate the Agreement without prejudice to any other rights or remedies which may be available to such party.

17.4 Bankruptcy

This Agreement may be terminated by a party in the event the other party files a petition in bankruptcy, is adjudicated a bankrupt, makes an assignment for the benefit of its creditors, or otherwise seeks relief under or pursuant to any bankruptcy, insolvency or reorganization statute or proceeding, or if a petition in bankruptcy is filed against it which is not dismissed within sixty (60) days or proceedings are taken to liquidate the assets of such party (each a "**Bankruptcy Event**").

17.5 Remedies upon Termination

In the event of termination or expiration of this Agreement, in addition to any other remedies available to either of the parties:

- (i) Nordion shall use Commercially Reasonable Efforts to terminate all activities under this Agreement immediately;

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- (ii) within forty-five (45) days of such termination, each party, at and pursuant to the request of the other, shall destroy (with written certification thereof) or deliver to the other the Confidential Information, documentation and other information belonging to the other party, retaining one archival copy thereof as necessary for compliance with applicable laws and regulations and administration of obligations under this Agreement;
- (iii) all licenses granted by Navidea to Nordion under this Agreement shall immediately terminate;
- (iv) within sixty (60) days of such termination all Precursor and Reference Standards remaining in inventory shall, at Navidea's option and expense (subject to a quotation provided by Nordion and payable in advance at the request of Nordion), be disposed of or returned by Nordion to Navidea;
- (v) upon the termination of this Agreement for any reason, except a material breach by Nordion, Navidea shall reimburse Nordion for any reasonable expenses incurred in inventory write-down, Facility decommissioning and any related waste disposal costs and, only for employees specifically hired in support of the [¹²³I]NAV5001 program, employee(s) severance as a result of or arising from discontinuation of the Manufacture of [¹²³I]NAV5001;
- (vi) Navidea shall pay to Nordion any undisputed amounts otherwise due within thirty (30) days of the date of termination.

ARTICLE 18 – SURVIVAL

18.1 Consequences of Termination or Expiration

All Sections which by their nature must survive in order to give effect to their intent and meaning shall survive termination or expiration of this Agreement, including, without limitation, Articles 8, 10.2, 10.3, 13, 14.4, 14.5, 14.7, 14.8, 15, 16, 17.5, 18, 19, 20, 22.1, 23, 24, 25, 26, 27, 28, and 29.

ARTICLE 19 – NOTICES

19.1 Any notice to be sent to a party hereunder shall be forwarded to:

Nordion at: Nordion (Canada) Inc.
447 March Road
Ottawa, ON K2K 1X8
Attention: Vice President, Marketing, Sales and Business Development
Fax: 613-592-0767
with copy to : Senior Vice President and General Counsel

Navidea at: Navidea
425 Metro Place North, Suite 450
Dublin, OH 43017-1367, USA
Attention: Chief Executive Officer
Fax: 614-793-7520

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Any notice required or authorized to be given by a party to the other in accordance with the provisions of this Agreement shall, unless otherwise specifically stipulated, be in writing and delivered personally, by a nationally recognized overnight courier, or if by electronic facsimile confirmed by certified or registered mail. Notice shall be deemed delivered upon receipt.

ARTICLE 20 – ASSIGNMENT

20.1 No Assignment

This Agreement shall enure to the benefit of and shall be binding upon the heirs, executors, administrators, successors and permitted assigns of the parties. Neither Nordion nor Navidea shall assign this Agreement or any portion of this Agreement without the written approval of the other party, which approval shall not be unreasonably or untimely withheld; provided, however, that either party may assign this Agreement (including without limitation all of its respective rights and interests in the license granted under section 10.1), upon written notice and without the other's consent in connection with the sale of all or substantially all of its assets or the business to which this Agreement pertains, to a third party (provided such third party has agreed to accept assignment and assume the obligations and liabilities under this Agreement) or in connection with a merger, consolidation or similar transaction involving such party.

ARTICLE 21 – COMPLIANCE

21.1 Compliance with Laws

This Agreement and Nordion's and Navidea's obligations hereunder shall be carried out in all material respects in compliance with all applicable laws, by-laws, rules, regulations and orders of all applicable Federal, State, Provincial and Municipal governments. Navidea agrees to comply with all applicable export and import control laws. Nordion shall be responsible for all export licenses, authorizations and other customs formalities necessary for the export of [¹²³I]NAV5001 from Canada. Navidea acknowledges and agrees that Nordion may, in its sole discretion and without liability whatsoever to Navidea or any third party, terminate or delay the supply of product under this Agreement (notwithstanding an accepted order) should Nordion, acting in good faith, have reasonable grounds to believe: (a) Navidea may have violated or will violate any U.S. import controls legislation or regulations; (b) the Canadian or other applicable government body or authority or international organization of which Canada is a member or to which it adheres issues an embargo, sanction or advisory, or other export control or end user restriction; or (c) the delivery destination or area through which the shipment must pass is unsafe for reasons including, but not limited to, physical or environmental conditions, war, revolution, civil commotion, acts of terrorism, or acts of public enemies or where government advisories are in effect.

21.2 Anti-Corruption

In performance of this Agreement Nordion and Navidea and their respective personnel, agents and representatives shall at all times during the Term abide by all applicable, obligations imposed by the anti-bribery laws and foreign corrupt practices laws of all applicable jurisdictions in which the services are rendered, or obligations are carried out, and the laws of any other jurisdiction in which Navidea or any of its personnel, agents or representatives conducts business in relation to dealing with payments to governments or related persons or officials, or a company, for the purpose of obtaining or retaining business for or with, or directing business to, any person. For greater certainty, the foregoing laws shall include, among others, the *Criminal Code Amendment (Bribery of Foreign Public Officials) Act 1999* and the *Competition and Consumer Act 2010* of Australia, the *Foreign Corrupt Practices Act* of the United States of America, the *Lobbyists Registration Act* (Canada), the *Corruption of Foreign Public Officials Act* (Canada), the *Bribery Act 2010* (United Kingdom), and the *Criminal Code* of Canada. The parties agree that no portion of monies paid, or payable, in connection with its performance of this Agreement shall, directly or indirectly, be paid, received, transferred, loaned, offered, promised or furnished to or for the use of an officer or employee of any institution, government department, agency, instrumentality or corporation thereof, or any political party or any official of such party or candidate for office or any person acting for or on behalf of any of the foregoing, for the purpose of obtaining or retaining business for, or with, or directing business to, any person.

ARTICLE 22 – NON-WAIVER AND FORCE MAJEURE

22.1 Non-Waiver of Rights

Failure by either party to enforce at any time any of the provisions of this Agreement shall not be construed as a waiver of its rights hereunder. Any waiver of a breach of any provision hereof shall not be effective unless in writing and shall not affect either party's rights in the event of any additional breach.

22.2 Force Majeure

Neither party shall be liable to the other for failure to perform or delay in performing its obligations under this Agreement by virtue of the occurrence of an event of Force Majeure. In the event such Force Majeure affecting either party continues for more than ninety (90) days the party not subject of the Force Majeure may, upon thirty (30) days written notice, terminate this Agreement. “**Force Majeure**” shall mean an occurrence arising from unforeseen circumstances beyond a party’s reasonable control which prevents, delays or interferes with the performance by such party of any of its obligations hereunder including without limitation an event that occurs by reason of any act of God, flood, power failure, fire, explosion, casualty or accident, failure, inability or incapacity of suppliers or usual suppliers to have available for supply sufficient raw materials, equipment or machinery, or war, revolution, civil commotion, acts of public enemies, act of terrorism, blockage or embargo, interruption of or delay in transportation, strike or labor disruption.

In the event of Force Majeure, the party affected shall promptly notify the other party and shall exert Commercially Reasonable Efforts to eliminate, cure or overcome such event and to resume performance of its obligations.

In the event that such Force Majeure affects Isotope, Nordion shall use Commercially Reasonable Efforts to identify a then-existing alternative source of Isotope supply. Any incremental cost incurred by Nordion subsequent to entering into this Agreement in obtaining Isotope from a then existing alternative supplier for Manufacture of [¹²³I]NAV5001, shall be borne on a pass-through basis by Navidea. All costs and expenses, including, but not limited to, qualifying and validating an existing alternative supplier of Isotope for use in the Process shall be borne by Navidea. If Navidea elects not to bear the incremental cost, Manufacture of [¹²³I]NAV5001 shall be suspended during the period of Force Majeure, without liability to either party.

ARTICLE 23 – INSURANCE

23.1 Nordion Insurance

Without limiting any other obligation or liability hereunder, Nordion, at its expense, during the Term of this Agreement, shall obtain and maintain insurance coverage with limits and conditions not less than those specified below:

- (i) Commercial General Liability insurance (including product liability insurance) with a per-occurrence limit of not less than [*];
- (ii) Workers’ Compensation insurance in accordance with the statutory limits and requirements of the Province of British Columbia, Canada.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

In the event that the above described insurance policies are written on a claims-made basis, then such policies shall be maintained during the Term and for a period of not less than two (2) years thereafter. The insurance limits shall be in Canadian dollars or equivalent.

Navidea shall be named as additional insured under the Commercial General Liability insurance policy. Upon request, Nordion agrees to provide a Certificate of Insurance to Navidea evidencing the aforementioned insurance required and Navidea's additional insured status. Nordion will not be deemed to be relieved of any liability or responsibility because of the fact that it maintains (or does not maintain) insurance. The certificate(s) will also state that Nordion's insurer will endeavor to provide Navidea thirty (30) days written notice prior to any cancellation or the policy's expiration date. The Commercial General Liability insurance required under this Agreement shall be obtained from an insurance carrier with an A.M. Best rating of at least A-.

23.2 Navidea Insurance

Without limiting any other obligation or liability of Navidea, under this Agreement, Navidea agrees that during the Term of this Agreement, Navidea shall obtain and maintain insurance coverage with limits and conditions not less than those specified below:

- (i) Commercial General Liability insurance (excluding products liability insurance) with a per-occurrence limit of not less than [*] and a commercial umbrella policy with a per-occurrence limit of not less than [*];
- (ii) Products liability insurance with a per-occurrence limit of not less than [*];
- (iii) Workers' Compensation insurance with statutory limits per state of hire, and Employers Liability Insurance with limits of a minimum of [*] per accident.

In the event that any of the above described insurance policies are written on a claims-made basis, then such policy (ies) shall be maintained during the Term of this Agreement and for a period of not less than two (2) years thereafter.

Nordion shall be named as an additional insured under each of the Commercial General Liability, Products Liability and Commercial Umbrella policy. Upon request, Navidea agrees to provide a Certificate of Insurance to Nordion evidencing the aforementioned insurance required and Nordion's additional insured status. Navidea will endeavor to provide Nordion thirty (30) days written notice of any cancellation prior to the policy's expiration date. During the Term of the contract, Navidea will maintain property insurance, to insure the physical loss of its inventory and list the Nordion site as an insured location. Each insurance policy which is required under this Agreement shall be obtained from an insurance carrier with an A.M. Best rating of at least A-.

ARTICLE 24 – PUBLICATION

24.1 Publicity

The parties agree that, except as may otherwise be set out in this Agreement or be required by applicable laws, regulations, rules or orders or in connection with obtaining regulatory approvals for [¹²³I]NAV5001, no information concerning this Agreement and the transactions contemplated herein shall be made public by either party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed. In the event either party decides to issue a press release announcing the execution of this Agreement, it shall not do so without the prior written approval of the other party, which shall not be unreasonably withheld.

A copy of any proposed press release shall be provided to the other party for approval at least ten (10) business days prior to any proposed release.

In the event that this Agreement or any portion of its contents is required to be disclosed by Navidea or Nordion pursuant to Security Exchange Commission rules or regulations, the FDA, or other federal or state authorities, Navidea or Nordion, as the case may be, shall provide reasonable notice to the other prior to any such disclosure in order that, to the extent possible (and as permitted by applicable law) permitting such party to redact this Agreement of sensitive or confidential information while enabling the other party to comply with the applicable laws, rules and regulations.

ARTICLE 25 – INDEPENDENT CONTRACTOR

25.1 No Joint Venture

The parties agree that with respect to the transactions contemplated herein that they shall both be acting as independent contractors and nothing herein shall constitute or create a joint venture, partnership or employer-employee relationship, nor shall anything herein constitute either party as an agent, representative or distributor of the other for any purpose whatsoever.

ARTICLE 26 – SEVERABILITY

26.1 Invalid Provisions

If any provision or term of this Agreement is found unenforceable under any of the laws or regulations applicable thereto, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement to effect the original intent of the parties as closely as possible in a mutually acceptable manner, in order that the transaction contemplated hereby be consummated as originally contemplated to the greatest extent possible.

ARTICLE 27 – AGREEMENT

27.1 Entire Agreement

This Agreement, including the Schedules hereto which are incorporated herein, constitute the entire agreement of the parties with respect to the subject matter hereof and supersedes all proposals, oral or written, and all negotiations, conversations, or discussions. This Agreement may not be modified, amended, rescinded, canceled or waived, in whole or in part, except by written amendment signed by both parties hereto. In the event of a conflict between a term of this Agreement and any Schedule or Quality Agreement, the terms of this Agreement shall govern. The captions or headings herein are solely for convenience and have no effect on the meaning or interpretation of this Agreement.

ARTICLE 28 – DISPUTE RESOLUTION

28.1 Except as otherwise set out or provided for in this Agreement, in the event that at any time during the Term of this Agreement, a disagreement, dispute, controversy or claim should arise with respect to the interpretation or application of this Agreement, the parties will attempt, in good faith, to resolve their difference for a period of ten (10) days following written notice from one party to the other specifying such disputes. In the event the parties are unable to agree on the resolution of the dispute during such ten (10) day period or any extension thereof that the parties agree to in writing, either party will be free to take any action and seek any remedy it may have, in law or in equity, including specific performance and injunctive relief. Notwithstanding the foregoing, either party may take any action and seek any remedy it may have, in law or in equity, without having fully complied with the above dispute resolution process, in order to avoid expiration of any applicable statute of limitations or as otherwise necessary to prevent irreparable harm.

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

ARTICLE 29 – LAW

29.1 Applicable Law

This Agreement shall be governed and construed in accordance with the laws of the Province of Ontario, Canada, without reference to its principles on conflict of laws. The application of the United Nations Convention on Contracts for the International Sale of Goods is expressly excluded.

ARTICLE 30 – EXECUTION

30.1 This Agreement may be executed in two or more counterparts, each of which together shall be deemed an original, but all of which together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

[SIGNATURE PAGE FOLLOWS]

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

IN WITNESS WHEREOF the parties hereto have executed this Agreement as of the date first above written.

NORDION (CANADA) INC.

NAVIDEA BIOPHARMACEUTICALS, INC.

/s/ Scott McIntosh

/s/ Mark J. Pykett

Nordion Representative (Signature)

Navidea Representative (Signature)

Scott McIntosh

Mark J. Pykett

Name

Name

Chief Operating Officer, Specialty Isotopes & General Manager,
Sterilization Technologies

Chief Executive Officer

Title

Title

May 10, 2013

May 10, 2013

Date

Date

SCHEDULE A

Facility Program, Facility Milestones and Project Schedule

The Facility Program outlined in this Schedule A provides for the return to operation of the Facility for the Manufacture of [¹²³I]NAV5001 for Navidea clinical studies in accordance with the project schedule outlined below and further set out in Table 1. There are 4 major milestones that must be satisfied pursuant to the [¹²³I]NAV5001 Clinical Supply Agreement ("Agreement") of which this Schedule A is a part. Table 1 describes the tasks entailed in more detail, the time necessary to accomplish those tasks, and the dates to complete each milestone. The finish dates of the tasks and the entire schedule is subject to the start date.

Milestone 1- Facility Ready

Description

[*]

Deliverables

- [*]

Milestone 2 – [*]

Description

[*]

Deliverables:

- [*]

Milestone 3 – First Validation Run

Description

[*]

Deliverables:

- [*]

Milestone 4 – Ready for Clinical Supply

Description

[*]

Deliverables:

- [*]

Facility resources for Manufacturing [¹²³I]NAV5001

In the clinical supply room (112B) the following Equipment is dedicated to [¹²³I]NAV5001

- [*]
- [*]
- [*]
 - o [*]
 - o [*];
 - (1)[*]
 - (1)[*]
 - (1)[*]
 - (1)[*]
 - (2)[*]
 - (1)[*]
 - o [*]
 - o [*];
 - (1)[*]
 - o [*]
 - o [*]
 - o [*]
- [*].

The general features of room 112B are:

- [*]
- [*]
- [*]

Other equipment (not in clinical supply room) dedicated for the manufacture of [¹²³I]NAV5001:

- [*]
 - o (1) [*]
 - o (1) [*]
 - o (1) [*]
 - o (1) [*]

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Non-dedicated support services used for the Manufacturing of [¹²³I]NAV5001:

- [*]
- [*]
- [*]
- [*]
- [*]
- [*]

[*]

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Table 1.
Program Schedule

ID	Task Name	Duration	Start	Finish	Predecessors
1	[*]	[*]	[*]	[*]	[*]
2	[*]	[*]	[*]	[*]	[*]
3	[*]	[*]	[*]	[*]	[*]
4	[*]	[*]	[*]	[*]	[*]
5	[*]	[*]	[*]	[*]	[*]
6	[*]	[*]	[*]	[*]	[*]
7	[*]	[*]	[*]	[*]	[*]
8	[*]	[*]	[*]	[*]	[*]
9	[*]	[*]	[*]	[*]	[*]
10	[*]	[*]	[*]	[*]	[*]
11	[*]	[*]	[*]	[*]	[*]
12	[*]	[*]	[*]	[*]	[*]
13	[*]	[*]	[*]	[*]	[*]
14	[*]	[*]	[*]	[*]	[*]
15	[*]	[*]	[*]	[*]	[*]
16	[*]	[*]	[*]	[*]	[*]
17	[*]	[*]	[*]	[*]	[*]
18	[*]	[*]	[*]	[*]	[*]
19	[*]	[*]	[*]	[*]	[*]
20	[*]	[*]	[*]	[*]	[*]
21	[*]	[*]	[*]	[*]	[*]
22	[*]	[*]	[*]	[*]	[*]
23	[*]	[*]	[*]	[*]	[*]
24	[*]	[*]	[*]	[*]	[*]
25	[*]	[*]	[*]	[*]	[*]
26	[*]	[*]	[*]	[*]	[*]
27	[*]	[*]	[*]	[*]	[*]
28	[*]	[*]	[*]	[*]	[*]
29	[*]	[*]	[*]	[*]	[*]
30	[*]	[*]	[*]	[*]	[*]
31	[*]	[*]	[*]	[*]	[*]
32	[*]	[*]	[*]	[*]	[*]
33	[*]	[*]	[*]	[*]	[*]
34	[*]	[*]	[*]	[*]	[*]
35	[*]	[*]	[*]	[*]	[*]
36	[*]	[*]	[*]	[*]	[*]
37	[*]	[*]	[*]	[*]	[*]
38	[*]	[*]	[*]	[*]	[*]
39	[*]	[*]	[*]	[*]	[*]
40	[*]	[*]	[*]	[*]	[*]
41	[*]	[*]	[*]	[*]	[*]
42	[*]	[*]	[*]	[*]	[*]
43	[*]	[*]	[*]	[*]	[*]
44	[*]	[*]	[*]	[*]	[*]
45	[*]	[*]	[*]	[*]	[*]
46	[*]	[*]	[*]	[*]	[*]
47	[*]	[*]	[*]	[*]	[*]
48	[*]	[*]	[*]	[*]	[*]
49	[*]	[*]	[*]	[*]	[*]
50	[*]	[*]	[*]	[*]	[*]
51	[*]	[*]	[*]	[*]	[*]
52	[*]	[*]	[*]	[*]	[*]

53	[*]	[*]	[*]	[*]	[*]
54	[*]	[*]	[*]	[*]	[*]
55	[*]	[*]	[*]	[*]	[*]
56	[*]	[*]	[*]	[*]	[*]
57	[*]	[*]	[*]	[*]	[*]
58	[*]	[*]	[*]	[*]	[*]
59	[*]	[*]	[*]	[*]	[*]
60	[*]	[*]	[*]	[*]	[*]
61	[*]	[*]	[*]	[*]	[*]
62	[*]	[*]	[*]	[*]	[*]
63	[*]	[*]	[*]	[*]	[*]
64	[*]	[*]	[*]	[*]	[*]
65	[*]	[*]	[*]	[*]	[*]
66	[*]	[*]	[*]	[*]	[*]
67	[*]	[*]	[*]	[*]	[*]
68	[*]	[*]	[*]	[*]	[*]
69	[*]	[*]	[*]	[*]	[*]
70	[*]	[*]	[*]	[*]	[*]
71	[*]	[*]	[*]	[*]	[*]
72	[*]	[*]	[*]	[*]	[*]
73	[*]	[*]	[*]	[*]	[*]
74	[*]	[*]	[*]	[*]	[*]
75	[*]	[*]	[*]	[*]	[*]
76	[*]	[*]	[*]	[*]	[*]
77	[*]	[*]	[*]	[*]	[*]
78	[*]	[*]	[*]	[*]	[*]

SCHEDULE B

[¹²³I]NAV5001 Specifications

	<u>Specifications</u>
Animal products	[*]
	[*]
Formulation	[*]
	[*]
Primary Packaging	[*]
	[*]
Calibration time	[*]
	[*]
Doses per vial	[*]
	[*]
Maximum volume	[*]
	[*]
Sterilization process	[*]
	[*]
Final Product Release	[*]
Visual Inspection	[*]
pH	[*]
Activity Concentration	[*]
Total Activity	[*]
Radionuclidic Identity	[*]
Radionuclidic Purity	[*]
Radiochemical Identity	[*]
Radiochemical Purity	[*]
Chemical Purity	[*]
Endotoxin	[*]
Sterility	[*]

Confidential Treatment – Asterisked material has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

SCHEDULE C

Fees for Facility Program and return to operation of the Facility for Clinical Trials' supply of [¹²³I]NAV5001

Payment Milestones	Initial Payment	Milestone 1	Milestone 2	Milestone 3	Milestone 4	Total
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]

Notes:

- 1) Navidea will pay to Nordion for the services set forth in this Agreement plus all applicable taxes on the amounts mentioned above.
- 2) The scope excludes any travel by Nordion employees.

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SCHEDULE D

Batch Fees

[¹²³I]NAV5001 Batch Fees

A. [*]

B. [*]

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SCHEDULE E

INTERCOMPANY QUALITY AGREEMENT

Navidea Biopharmaceuticals, Inc.
425 Metro Place North, Suite 450
Dublin, OH 43017-1367, USA
(hereafter called “**Navidea**”)

AND

Nordion (Canada) Inc.
447 March Road
Ottawa, Ontario, Canada K2K 1X8
(hereafter called “**Nordion**”)

Page 47 of 61

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Quality Assurance Agreement (QAA)
[¹²³I]NAV5001 Drug Product Manufacture by
Nordion (Canada) Inc.

QAA-009 Revision A

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Purpose

This Quality Assurance Agreement (QAA) defines the activities and responsibilities between the two parties, Nordion (Canada) Inc. (“NORDION”) and Navidea Biopharmaceuticals Inc. (“NAVIDEA”) with respect to the [¹²³I]NAV5001 drug product manufacture.

Scope

This QAA includes the activities associated with the production, handling, analysis, release, warehousing, and distribution of [¹²³I]NAV5001. This agreement is subject to the terms of a Clinical Supply Agreement (CSA) between NORDION and NAVIDEA that defines the specific business terms upon which NORDION is providing services to NAVIDEA. The respective parties also agree to perform the activities identified herein. In the case of discrepancy between this QAA and the [¹²³I]NAV5001 Clinical Supply Agreement, the [¹²³I]NAV5001 Clinical Supply Agreement shall prevail.

Procedures for amendments

This QAA may be amended from time to time in writing by the mutual written consent of both parties. Amendments to the QAA are routed to Quality at NORDION and NAVIDEA for review and approval, and to ensure compliance with the Regulatory File (IND, NDA, MAA, etc.). The periodic updating of Appendix 3, Key Contacts, does not constitute a formal revision to the document and therefore does not need written approval.

Term / Termination of Agreement

The term of this QAA shall begin on the date of the last approval signature (the “Approval Date”) and will expire on the latter of (i) the date of expiration of the CSA or (ii) three (3) years from the QAA Approval Date, except as noted below in the survival clause.

Survival Clause

The provisions under sections *Regulatory Authorizations and GMP Compliance, Testing and Analysis, Record Retention, and Complaints and Adverse Events* shall survive termination of this QAA as required by any applicable government agency.

Appendix 1. Responsibility Delegation checklist

SECTION	RESPONSIBILITIES	NAVIDEA	NORDION
1. Production			
1.1.	Production of [¹²³ I]NAV5001 will be in compliance with Federal, State, and Local laws and regulations and guidelines for pharmaceutical manufacturing, the Regulatory File, and NAVIDEA approved specifications. This will include compliance with regional Good Manufacturing Practices (GMP) (e.g., 21 CFR Parts 210 and 211 etc.).		X
1.2.	Automated systems, electronic, signatures and electronic records will comply with 21 CFR Part 11 requirements.		X
1.3.	NAVIDEA QA will audit and assess level of compliance in periodic audits.	X	
1.4.	NAVIDEA CMC will provide NORDION with production/technical information that includes specialized equipment required for manufacturing [¹²³ I]NAV5001.	X	
1.5.	Provide NORDION with copies of those portions of the Regulatory File and any subsequent amendments that are applicable to the manufacturing of [¹²³ I]NAV5001 at NORD.	X	
1.6.	NORDION will establish and maintain a Master Batch Record (MBR), and manufacture and test the product in accordance with the NAVIDEA approved MBR and specifications.		X
1.7.	NORDION will establish labeling and packaging requirements in accordance with the Regulatory File.		X
1.8.	Upon request NORD, and under the terms of the [¹²³ I]NAV5001 Clinical supply agreement, will allow a NAVIDEA representative to be on site during the manufacture of a batch, but is not allowed in the ‘suite’ during the production process.		X

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SECTION	RESPONSIBILITIES	NAVIDEA	NORDION
1.9.	Promptly notify NAVIDEA QA and document, investigate, and resolve non-conformance, OOS, and deviations from the MBR and/or NAVIDEA approved specifications. These activities will be remediated between NAVIDEA and NORDION prior to final disposition of the batch.	X	X
1.10.	Conduct an annual review of batches. Evaluate and assess whether corrective actions or revalidations should be undertaken. Submit the approved annual review to NAVIDEA.		X
1.11.	NAVIDEA will promptly notify NORDION if there is a change to the specifications submitted to the Regulatory File.	X	
2. Testing and Analysis			
2.1.	Where applicable, transfer a copy of the validated analytical test method(s) to NORDION.	X	
2.2.	Test product according to NAVIDEA approved specifications, analytical and microbial test methods and procedures. Provide a copy of the Product Release Form (PRF) to NAVIDEA.		X
2.3.	Conduct sampling in accordance with approved specifications within the batch record.		X
2.4.	Within two (2) business days inform NAVIDEA QA of and assist in investigating OOS results identified in any testing conducted by NORDION or an independent lab contracted by NORDION and provide documentation relating to such investigation with the batch record applicable to the batch containing the OOS test result.		X
2.5.	Complete investigations according to the requirements, including timeliness, in the standard operating procedures. Non-conforming product will be placed on QA Hold until such non-conformance is adequately resolved by completing OOS investigations and reviewing planned deviations.	X	X
2.6.	Promptly inform NORDION of and investigate OOS results identified in any testing conducted by a NAVIDEA designated lab. Promptly provide NORDION copies of documentation relating to such investigations for inclusion with the batch record applicable to the batch containing the OOS test result.	X	

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<u>SECTION</u>	<u>RESPONSIBILITIES</u>	<u>NAVIDEA</u>	<u>NORDION</u>
2.7.	Within two (2) business days notify NORDION of any recall and/or confirmed stability failure (if applicable).	X	
3. Batch Record Review and Release			
3.1.	NORDION QA will review and approve the PBR to confirm compliance with: <ul style="list-style-type: none"> • Specifications, • Regulatory File, • Applicable laws, and • Acceptance criteria requirements 		X
3.2.	Product Release Forms (PRFs) will be provided to confirm that lots of [¹²³ I]NAV5001 were manufactured, packaged and tested in accordance with cGMP. The PRF will identify the master batch record documents, and list any incident reports and investigations associated with the batch. The PRF will present a recording of the results of testing against the established specifications and the signature and date of the NORDION QA representative who released the batch.		X
3.3.	Perform necessary studies to qualify shipping procedures for the product.	X	
3.4.	Provide specifications for the shipment of product. Such instructions shall include, when appropriate, packaging, labeling, temperature and humidity controls, including methods to monitor these conditions.	X	
3.5.	Ensure product is stored, handled and shipped to the specified destinations in accordance with NAVIDEA instructions.		X
4. Regulatory Actions and Inspections			
4.1.	Notify the other party of any regulatory agency inspection, specific to “[¹²³ I]NAV5001”, applicable portions of any adverse finding from a regulatory agency within two (2) business days of occurrence and any applicable portions of subsequent response(s) to the regulatory agency directly related to the product.	X	X

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SECTION	RESPONSIBILITIES	NAVIDEA	NORDION
4.2.	Notify the other party of any regulatory agency's request for samples of product or batch records within two (2) business days of receipt.	X	X
4.3.	Notify the other party of any requests for information, notices of violations or other communication from a regulatory agency relating to environmental, occupational health (i.e. illness) and safety compliance, within two (2) business days of receipt.	X	X
5. Compliance of Specifications With Regulatory File(s) and Change Control			
5.1.	Upon NORDION's reasonable request, NAVIDEA shall provide updates to Nordion on submissions to the FDA with respect to [123I]NAV5001.	X	
5.2.	Provide NAVIDEA with any proposed change that would negatively or positively impact the identity, quality, durability, purity, safety or effectiveness of the Company's products in writing to NAVIDEA's QA contact for review and disposition before implementation.		X
5.3.	Ensure that specifications contained in the CSA and MBR comply with the Regulatory File.	X	X
5.4.	Submit and discuss any proposed changes to the specifications to the other party for review and approval, prior to the implementation of such changes and the submission of any such changes to the regulatory agency. The exchange of comments between the parties shall occur within fifteen (15) business days.	X	X
5.5.	NAVIDEA shall have final authority over any change to a specification, the facilities, processing, or analytical testing that may directly affect the product.		
5.5.	Notify NAVIDEA of proposed additions or changes in subcontracted service providers/suppliers that would impact the compliance status of the Regulatory File.		X
5.6.	Liaison with regulatory authorities for the approval, maintenance and updating of product specifications in the Regulatory File.	X	(if requested)

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SECTION	RESPONSIBILITIES	NAVIDEA	NORDION
6. Record and Sample Retention			
	Maintain the Batch production records and other documentation related to the [123I]NAV5001 for the minimum period required by applicable laws, regulations and statutes.		
6.1.	Consistent with NORDION Record Retention SOP, NORDION will notify NAVIDEA that records have reached the end of the required retention period and request written authorization prior to destruction.	X	X
	NOTE: Original documents will be maintained at NORDION and copies provided to NAVIDEA		
6.2.	At termination of the CSA, and once NORDION has fulfilled its regulatory obligation, all original records will be shipped to a specified destination for record archival. NAVIDEA will inform the regulatory agency of the new records location.	X	X
6.3.	Consistent with NORDION SOPs, retain (or reserve) samples will be maintained for any Regulatory Final Intermediate (NAV5010) and [123I]NAV5001.		X
6.4.	Consistent with NORDION (Sample) Retention SOP, NORDION will notify NAVIDEA that samples have reached the end of the required retention period and request written authorization prior to destruction.		X
7. Safety and Security			
7.1.	NAVIDEA CMC will maintain safety, hazard, and handling data on any compound provided on Navidea's behalf and provide a copy of it to NORDION.	X	
7.2.	Ensure that access to the facility is through an appropriate security system and that visitors must sign in/out and be escorted during any site visit.		X
8. Complaints and Adverse Events			
8.1.	Collect and log information relating to product quality complaints and adverse drug events received by either NAVIDEA or NORDION and notify the other party within 2 business days of receipt.	X	X

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SECTION	RESPONSIBILITIES	NAVIDEA	NORDION
8.2.	Respond to regulatory agencies regarding product complaints and adverse drug events and file the necessary reports.	X	
8.3.	NORDION and NAVIDEA shall provide to each other notice either of them receives regarding the safety of the Precursor, Reference Standards or [¹²³ I]NAV5001, including information regarding any confirmed or unconfirmed adverse events within two (2) business days.	X	X
9. Product Recall and Withdrawal			
9.1.	NAVIDEA is responsible for the decision to initiate a product recall or withdrawal.	X	
9.2.	NAVIDEA is responsible to provide notification of the recall to third parties and to NORDION. NORDION must be informed of the decision to recall within two (2) business days.	X	
9.3.	Provide support to NAVIDEA, upon request, to facilitate a product recall.		X
9.4.	Responsible for final reconciliation of returned product following product recall or withdrawal.	X	X
10. Quality Agreement			
10.1.	Review this quality agreement annually and update as necessary.	X	X

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Appendix 2. Change History

Rev. Level	Rev. Date	Details		Description of Change
		Page	§	
A	15 MAR 2013	All	All	Initial Release

Appendix 3. Key Contacts

	Navidea	NORD
	[*] Phone: [*] Wireless: Fax: [*] [*]	[*] Phone: [*] Fax: [*] [*]
Quality Assurance and Regulatory	Backup: [*] Phone: [*] Wireless: Fax: [*] [*]	Back-up: [*] Phone: [*] Fax: [*] [*]
	[*] Phone: [*] Wireless: Fax: [*] [*]	[*] Phone: [*] Fax: [*] [*]
CMC Operations, Shipping, Logistics, Inventory	Backup: [*] Wireless: [*] [*]	Back-up: [*] Phone: [*] Fax: [*] [*]

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Appendix 4. Signature Page

Quality Assurance Agreement
Between
Nordion (Canada) Inc.
447 March Road
Ottawa, Ontario, Canada
and
Navidea Biopharmaceuticals, Inc.
425 Metro Place North, Suite 450
Dublin, Ohio 43017-1367

Written by:
Navidea Biopharmaceuticals, Inc.
Rebecca Csak, QA Compliance Specialist

Approved by:

Navidea Biopharmaceuticals, Inc.
David Casebier V.P., CMC

Date

Navidea Biopharmaceuticals, Inc.
Rodger Brown, V.P., Global Regulatory Operations & Quality Assurance

Date

Nordion (Canada) Inc.
Jeff Whyte, Director, Quality, Safety and Regulatory Affairs

Date

Nordion (Canada) Inc.
Ron McGregor, Vice-President, Regulatory and EHS Compliance

Date

SCHEDULE F

Initial Amounts to be Provided and Specifications for Precursor and Reference Standards

Initial Amounts to be Provided		
NAV5001	NAV5010	NAV5011
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

NAV5001 Analytical Information to be Supplied

Test	Specifications
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

NAV5010 Certificate of Analysis

Tests	Specifications
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

NAV5011 Analytical Information to be Supplied

Test	Specifications
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

SCHEDULE G

CHANGE IN SCOPE FORM

Effective Date: _____, 2013

This amendment shall form a change in scope order (“**Change in Scope Order**”) to the existing (INSERT SCHEDULE WHICH IS BEING MODIFIED) executed on _____, 2013 between Navidea Biopharmaceuticals, Inc. (hereinafter referred to as “**Navidea**”) and Nordion (Canada) Inc. (hereinafter referred to as “**Nordion**”). All Articles and provisions of the (INSERT SCHEDULE WHICH IS BEING MODIFIED) remain in effect and will apply to all subsequent amendments to that (INSERT SCHEDULE WHICH IS BEING MODIFIED), unless specifically stated as otherwise herein.

The purpose of this Change in Scope Order is set forth below.

Change in Scope Order Description for [¹²³I]NAV5001

- o
- o

Note to draft; Please insert columns

Total		

Original Project Budget:

Change Order No. 1 Value: _____

Revised Project Total:

See Attachment __ (Revised Schedule __) and __ (Revised Project Budget) incorporated herein by reference.

The scope changes will be charged to Navidea as follows:

- (i) Nordion's actual, documented cost for any materials, Equipment, third party services obtained via a Nordion purchase order, or Nordion inventory obtained via inventory requisition;
- (ii) Nordion labour rate is [*];

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- (iii) Nordion staff travel and accommodation shall be reimbursed to Nordion at cost, provided such amounts are approved by Navidea in advance. Time incurred during travel to destinations shall be billed to Navidea for each person half day or less of travel at the rate of [*].
- (iv) Third party services and materials will be estimated by Nordion based on the available information at the time the estimate is being prepared. Actual costs or exchange rates may vary as against original cost projections as firm quotations are obtained from vendors, favorably or unfavorably affecting the cost thereof.
- (v) All quoted amounts do not include any services, sales, use, value added and any and all other taxes for which Navidea is responsible. All such taxes will be paid by Navidea.



Press Release

Exhibit 99.1

FOR IMMEDIATE RELEASE

Navidea Biopharmaceuticals Signs Manufacturing and Supply Agreement with Nordion

– Nordion to Produce and Distribute Supplies of ^{123}I -labeled Drug Product NAV5001 for Late-Phase Clinical Trials –

DUBLIN, OHIO – May 15, 2013 – Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that it has entered into an agreement with Nordion (Canada) Inc. to produce and supply ^{123}I -labeled NAV5001 for Navidea's late-phase clinical trials.

The agreement focuses on Nordion's cGMP manufacturing and supply of NAV5001 clinical trial material to be produced at Nordion's Vancouver, British Columbia, facility. Accordingly, Nordion will radiolabel Navidea's precursor drug product with Iodine-123 to form [^{123}I]NAV5001, manage the logistics and make arrangements for shipment of NAV5001 to third-party clinical trial sites on behalf of Navidea. The agreement may serve as a predecessor to a commercial supply arrangement in the future.

"This manufacturing and supply agreement with Nordion moves us closer to commencing our critical NAV5001 clinical programs in the differential diagnosis of Parkinsonian Syndromes and Dementia with Lewy Bodies," stated Thomas Tulip, PhD, Navidea's President and Chief Business Officer. "Nordion has extensive expertise in high quality production of ^{123}I radiopharmaceuticals and a world class distribution system to reliably manage logistics to ensure that radiolabeled NAV5001 reaches clinical trial site destinations according to rigorous standards."

"We are proud that Navidea has chosen Nordion manufacturing and distribution services for one of its important neurological radiopharmaceuticals," said Tom Burnett, General Manager, Medical Isotopes, Nordion. "We offer a strong base of technical expertise, production and distribution services that we expect will enable Navidea to efficiently provide their investigational product candidate to doctors and medical centers involved in NAV5001 clinical trials throughout North America."

About NAV5001

Iodine-123 labeled NAV5001 is a patented, novel, small molecule radiopharmaceutical used with single photon emission computed tomography (SPECT) imaging to identify the status of specific regions in the brains of patients suspected of having Parkinson's disease. The agent binds to the dopamine transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a widely recognized hallmark of Parkinson's disease and other forms of Parkinsonism.

NAV5001 has been administered to more than 600 subjects in multi-phase clinical trials to date. Results from these clinical trials have demonstrated that NAV5001 has high affinity for DAT and rapid kinetics which enable the generation of clean diagnostic images quickly, beginning within approximately 20 minutes after injection. In addition to its potential use as an aid in the differential diagnosis of Parkinsonian syndromes and movement disorders, NAV5001 may also be useful in the diagnosis of DLB, which after Alzheimer's disease, is one of the most common forms of dementia.

- more -

About Nordion Inc.

Nordion Inc. (TSX: NDN) (NYSE: NDZ) is a global health science company that provides market-leading products used for the prevention, diagnosis and treatment of disease. We are a leading provider of targeted therapies, sterilization technologies, and medical isotopes that benefit the lives of millions of people in more than 60 countries around the world. Our products are used daily by pharmaceutical and biotechnology companies, medical-device manufacturers, hospitals, clinics and research laboratories. Nordion has approximately 500 highly skilled employees worldwide. Find out more at www.nordion.com and follow us at <http://twitter.com/NordionInc>.

About Navidea Biopharmaceuticals, Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent platforms – Lymphoseek[®], NAV4694, NAV5001 and RIGScan[™] – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit www.navidea.com.

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: Navidea Biopharmaceuticals – Brent Larson, CFO – (614) 822-2330
Investor Relations – Stern Investor Relations, Inc. — Beth DelGiacco – (212) 362-1200

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- end -