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

**AMENDMENT NO. 1
TO
FORM 10-K**

(Mark One)

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

For the fiscal year ended July 31, 2017

OR

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

For the transition period from _____ to _____

Commission file number 000-54318

ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation or organization)

98-0573252
(I.R.S. Employer
Identification Number)

**5820 Nancy Ridge Drive
San Diego, CA 92121**
(Address of principal executive offices)(Zip Code)

7(855) 662-6732
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Class:</u>	<u>Name of Exchange on which Registered:</u>
Common Stock, par value \$0.0001 per share	The NASDAQ Stock Market LLC (NASDAQ Capital Market)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging growth company []

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of January 31, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$22,001,286, computed by reference to the price at which the registrant's common stock was last sold on such date, as reported by the NASDAQ Capital Market. Shares of common stock held by the registrant's officers and directors and holders of 10% or more of the outstanding shares of the registrant's common stock have been excluded from this calculation because such persons may be deemed to be affiliates of the registrant; however, this determination of affiliate status is not, and shall not be considered, a determination of affiliate status for any other purpose.

As of November 27, 2017, there were 35,417,727 outstanding shares of the registrant's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for its next annual meeting of stockholders, which is expected to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended July 31, 2017, are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated therein.

EXPLANATORY NOTE

The undersigned registrant is filing this Amendment No. 1 to Form 10-K (this “Amendment”) for the sole purpose of correcting certain errors in the Exhibit Index included in its Annual Report on Form 10-K for its fiscal year ended July 31, 2017 (the “Original Annual Report”), as filed with the Securities and Exchange Commission (the “SEC”) on October 25, 2017. As a result, and in accordance with applicable rules of the SEC, this Amendment hereby amends and restates in its entirety Item 15 of Part IV of the Original Annual Report as set forth herein.

Except as expressly described above and as set forth herein, this Amendment does not modify the Original Annual Report in any way, including, without limitation, to reflect events occurring after the date of, or update any of the disclosures included in, the Original Annual Report. Accordingly, this Amendment should be read in conjunction with the Original Annual Report and with the registrant’s other filings with the SEC subsequent to the Original Annual Report.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

- (a)(1) The financial statements of OncoSec Medical Incorporated listed in the Index to Consolidated Financial Statements are filed as part of this report under Item 8 — Financial Statements and Supplementary Data.
- (a)(2) All financial statement schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto included in this report.
- (a)(3) The exhibits listed in the Exhibit Index, which appears immediately before the signature page of this report and is incorporated herein by reference, are filed, furnished or incorporated by reference as part of this report.

EXHIBIT INDEX

The following exhibits are being filed with or incorporated by reference in this report:

Exhibit Number	Description of Exhibit
3.1	<u>Articles of Incorporation of OncoSec Medical Incorporated, as amended (previously filed as Exhibit 3.1 to the Original Annual Report)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.6 to our Current Report on Form 8-K, filed on March 6, 2012)</u>
4.1	<u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed on December 19, 2012)</u>
4.2	<u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed on September 19, 2013)</u>
4.3	<u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed on June 5, 2014)</u>
4.4	<u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on November 5, 2015)</u>
4.5	<u>Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on May 24, 2016)</u>
4.6	<u>Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K, filed on May 24, 2016)</u>
10.1†	<u>Cross-License Agreement, dated March 24, 2011 by and between OncoSec Medical Incorporated and Inovio Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed on June 14, 2011)</u>
10.2#	<u>Employment Agreement with Punit Dhillon dated May 18, 2011 (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q, filed on June 14, 2011)</u>
10.3#	<u>Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed on October 29, 2015)</u>
10.4#	<u>Executive Employment Agreement, effective July 6, 2015, by and between the Company and Richard Slansky (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed on December 8, 2015)</u>
10.5#	<u>OncoSec Medical Incorporated 2011 Stock Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed on December 7, 2016)</u>
10.6	<u>Lease Agreement, dated December 31, 2014, by and between the Company and ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on January 2, 2015)</u>
10.7	<u>Securities Purchase Agreement, dated as of November 3, 2015, by and among the Company and signatories thereto (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on November 5, 2015)</u>

- 10.8 [Placement Agency Agreement, dated as of November 3, 2015, by and between the Company and H.C. Wainwright & Co., LLC \(incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on November 5, 2015\)](#)
- 10.9 [Securities Purchase Agreement, dated as of May 22, 2016, by and among the Company and signatories thereto \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on May 24, 2016\)](#)
- 10.10 [Placement Agency Agreement, dated as of May 22, 2016, by and between the Company and H.C. Wainwright & Co., LLC \(incorporated by reference to Exhibit 10.2 our Current Report on Form 8-K, filed on May 24, 2016\)](#)
- 10.11*† [Clinical Trial Collaboration and Supply Agreement, dated as of May 10, 2017, by and between the Company and MSD International GmbH](#)
- 21.1* [Subsidiaries of the registrant](#)
- 23.1 [Consent of Independent Registered Public Accounting Firm, Mayer Hoffman McCann P.C. \(previously filed as Exhibit 23.1 to the Original Annual Report\)](#)
- 31.1 [Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934 \(previously filed as Exhibit 31.1 to the Original Annual Report\)](#)
- 31.2 [Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934 \(previously filed as Exhibit 31.2 to the Original Annual Report\)](#)
- 31.3* [Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934](#)
- 31.4* [Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934](#)
- 32.1 [Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 \(previously filed as Exhibit 32.1 to the Original Annual Report\)](#)
- 32.2 [Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 \(previously filed as Exhibit 32.2 to the Original Annual Report\)](#)
- 101.INS XBRL Instant Document (previously filed as Exhibit 101.INS to the Original Annual Report)
- 101.SCH XBRL Taxonomy Extension Schema Document (previously filed as Exhibit 101.SCH to the Original Annual Report)
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document (previously filed as Exhibit 101.CAL to the Original Annual Report)
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document (previously filed as Exhibit 101.DEF to the Original Annual Report)
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document (previously filed as Exhibit 101.LAB to the Original Annual Report)
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document (previously filed as Exhibit 101.PRE to the Original Annual Report)

* Filed herewith.

Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted or requested with respect to portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and these confidential portions have been redacted from the filing that is incorporated by reference. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ONCOSEC MEDICAL INCORPORATED

By: */s/ Daniel J. O'Connor*

Daniel J. O'Connor

Chief Executive Officer

Date: November 28, 2017

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

by and among

MSD International GmbH

and

OncoSec Medical Incorporated

Dated: May 10, 2017

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Schedule I – Data Sharing and Sample Testing Schedule

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this “**Agreement**”), is entered into as of May 10, 2017 (the “**Effective Date**”), by and among MSD International GmbH, having a place of business at Weystrasse 20, 6000 Luzern 6, Switzerland (“**Merck**”), and OncoSec Medical Incorporated, having a place of business at 5820 Nancy Ridge Drive, San Diego, California 92121 USA (“**Company**”). Merck and Company are each referred to herein individually as “**Party**” and collectively as “**Parties**”.

RECITALS

- A. Merck holds intellectual property rights with respect to the Merck Compound (as defined below).
- B. Company is developing the Company Compound (as defined below) for the treatment of certain tumor types.
- C. Merck is developing the Merck Compound for the treatment of certain tumor types.
- D. Company desires to sponsor a clinical trial in which the Company Compound and the Merck Compound would be dosed concurrently or in combination.
- E. Merck and Company, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Merck Compound and the Company Compound for the Study (as defined below).

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. Definitions.

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1. “**Affiliate**” means, with respect to either Party, a firm, corporation or other entity that, now or hereafter, directly or indirectly owns or controls said Party, or, now or hereafter, is owned or controlled by said Party, or is under common ownership or control with said Party. The word “**control**” as used in this definition means (a) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity or (b) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

1.2. “**Agreement**” means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

1.3. “**Alliance Manager**” has the meaning set forth in Section 3.10.3.

1.4. “**Applicable Law**” means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration (“**FDA**”), national regulatory authorities, the European Medicines Agency (“**EMA**”) and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a “**Regulatory Authority**” and collectively, “**Regulatory Authorities**”), and including cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU Data Protection Directive and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country’s or jurisdiction’s successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

1.5. “**Business Day**” means any day other than a Saturday, Sunday, or a day on which commercial banks located in the country where the applicable obligations are to be performed are authorized or required by law to be closed.

1.6. “**cGMP**” means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

1.7. “**Clinical Data**” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of each such Party’s performance of the Study; *provided however*, that Clinical Data does not include Sample Testing Results.

1.8. “**Clinical Quality Agreement**” has the meaning set forth in Section 8.2.

1.9. “**CMC**” means “**Chemistry Manufacturing and Controls**” as such term of art is used in the pharmaceutical industry.

1.10. “**Combination**” means the use or method of using the Company Compound and the Merck Compound in concomitant or sequential administration.

1.11. “**Company**” has the meaning set forth in the preamble.

1.12. “**Company Background Patents**” has the meaning set forth in Section 10.4.1.

1.13. “**Company Class Compound**” means any intratumorally-delivered plasmid containing a DNA sequence that encodes interleukin 12 (IL-12).

1.14. “**Company Compound**” means intratumoral plasmid interleukin 12 (pIL-12) with electroporation (IT-pIL-12-EP), excluding, however, any biosimilar version of intratumoral plasmid interleukin 12 (pIL-12) with electroporation (IT-pIL 12-EP) other than a biosimilar version Controlled by Company or its Affiliate.

1.15. “**Company Inventions**” has the meaning set forth in Section 10.2.

1.16. “**Compounds**” means the Company Compound and the Merck Compound. A “**Compound**” means either the Company Compound or the Merck Compound, as applicable.

1.17. “**Confidential Information**” means any information, Know-How or other proprietary information or materials furnished to one Party (“**Receiving Party**”) by or on behalf of the other Party (“**Disclosing Party**”) in connection with this Agreement, except to the extent that such information or materials: (a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party, as demonstrated by competent evidence; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; (d) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (e) was subsequently developed by the Receiving Party without use of the Disclosing Party Confidential Information, as demonstrated by competent evidence.

1.18. “**Continuing Party**” has the meaning set forth in Section 10.1.3.

1.19. “**Control**” or “**Controlled**” means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.20. “**CTA**” means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

1.21. “**Data Sharing and Sample Testing Schedule**” means the schedule attached hereto as Schedule I.

1.22. “**Defending Party**” has the meaning set forth in Section 14.2.3.

1.23. “**Delivery**” with respect to the Merck Compound has the meaning set forth in Section 8.4.1, and with respect to the Company Compound, the meaning set forth in Section 8.4.2.

1.24. “**Direct Manufacturing Costs**” has the meaning set forth in Section 6.11.

1.25. “**Disclosing Party**” has the meaning set forth in the definition of Confidential Information in Section 1.17.

1.26. “**Disposition Package**” has the meaning set forth in Section 8.8.1.

1.27. “**Effective Date**” has the meaning set forth in the preamble.

1.28. “**EMA**” has the meaning set forth in the definition of Applicable Law in Section 1.4.

1.29. “**Exclusions List**” has the meaning set forth in the definition of Violation in Section 1.84.

1.30. “**FDA**” has the meaning set forth in the definition of Applicable Law in Section 1.4.

1.31. “**Filing Party**” has the meaning set forth in Section 10.1.3.

1.32. “**Final Study Report**” has the meaning set forth in Section 3.11.

1.33. “**Force Majeure**” has the meaning set forth Article 16.

1.34. “**GAAP**” has the meaning set forth in Section 6.11.

1.35. “**GCP**” means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.

1.36. “**Government Official**” means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either of the Parties.

1.37. “**HIPAA**” has the meaning set forth in the definition of Applicable Law in Section 1.4.

1.38. “**IND**” means any Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an “Investigational Medicinal Product Dossier” filed or to be filed with Regulatory Authorities in the European Union.

1.39. “**Indirect Manufacturing Costs**” has the meaning set forth in Section 6.11.

Confidential Treatment Requested. Omitted Portions are Marked with [**] and have been Filed Separately with the Securities and Exchange Commission.**

1.40. “**Inventions**” means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together, (a) in the design or performance of the Study or (b) through use of unpublished Clinical Data.

1.41. “**Joint Development Committee**” or “**JDC**” has the meaning set forth in Section 3.10.1.

1.42. “**Joint Patent Application**” has the meaning set forth in Section 10.1.3.

1.43. “**Joint Patent**” means a patent that issues from a Joint Patent Application.

1.44. “**Jointly Owned Invention**” has the meaning set forth in Section 10.1.1.

1.45. “**Know-How**” means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.46. “**Liability**” has the meaning set forth in Section 14.2.1.

1.47. “**Manufacture**,” “**Manufactured**,” or “**Manufacturing**” means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafletting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.48. “**Manufacturer’s Release**” or “**Release**” has the meaning ascribed to such term in the Clinical Quality Agreement.

1.49. “**Manufacturing Site**” means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.7.

1.50. “**Merck**” has the meaning set forth in the preamble.

1.51. “**Merck Background Patents**” has the meaning set forth in Section 10.4.2.

1.52. “**Merck Compound**” means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody[****].

1.53. “**Merck Inventions**” has the meaning set forth in Section 10.3.

1.54. “**NDA**” means a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

Confidential Treatment Requested. Omitted Portions are Marked with [**] and have been Filed Separately with the Securities and Exchange Commission.**

1.55. “**Non-Conformance**” means, with respect to a given unit of Compound, (a) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound or (b) that such Compound failed to meet the applicable representations and warranties set forth in Section 2.3. Classification of the Non-Conformance is detailed in the Clinical Quality Agreement.

1.56. “**Non-Filing Party**” has the meaning set forth in Section 10.1.3.

1.57. “**Other Party**” has the meaning set forth in Section 14.2.3.

1.58. “**Opting-out Party**” has the meaning set forth in Section 10.1.3.

1.59. “**Party**” has the meaning set forth in the preamble.

1.60. “**PD-1 Antagonist**” means any small or large molecule that [****].

1.61. “**Person**” means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.

1.62. “**Pharmacovigilance Agreement**” has the meaning set forth in Section 5.1.

1.63. “**Project Manager**” has the meaning set forth in Section 3.10.1.

1.64. “**Protocol**” means the written documentation that describes the Study and sets forth specific activities to be performed as part of the conduct of the Study.

1.65. “**Receiving Party**” has the meaning set forth in the definition of Confidential Information.

1.66. “**Regulatory Approvals**” means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation and distribution of such Compound in the United States, Europe or other applicable jurisdictions for use in the Study.

1.67. “**Regulatory Authorities**” has the meaning set forth in the definition of Applicable Law in Section 1.4.

1.68. “**Regulatory Documentation**” means, with respect to the Compounds, all submissions to Regulatory Authorities in connection with the development of such Compounds, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include Clinical Data).

1.69. “**Related Agreements**” means the Pharmacovigilance Agreement and the Clinical Quality Agreement.

1.70. “**Right of Reference**” means the “right of reference” defined in 21 CFR 314.3(b), including with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party’s Compound, only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.

1.71. “**SAEs**” has the meaning set forth in Section 5.2.

1.72. “**Samples**” means biological specimens collected from subjects participating in the Study, including urine, blood and tissue samples.

1.73. “**Sample Testing**” means the analyses to be performed by each Party using the applicable Samples, as described in the Data Sharing and Sample Testing Schedule.

1.74. “**Sample Testing Results**” means those data and results arising from the Sample Testing performed by a Party.

1.75. “**Specifications**” means, with respect to a given Compound, the set of requirements for such Compound as set forth in the Clinical Quality Agreement.

1.76. “**Study**” means the multicenter, phase II, adaptive, open-label clinical trial to evaluate the safety and preliminary efficacy of the concomitant and/or sequenced administration of the Merck Compound and the Company Compound in patients with Stage III/IV Melanoma who are progressing on either the Merck Compound or nivolumab treatment.

1.77. “**Study Completion**” has the meaning set forth in Section 3.11.

1.78. “**Subcontractors**” has the meaning set forth in Section 2.4.

1.79. “**Subsequent Study**” has the meaning set forth in Section 3.14.1.

1.80. “**Term**” has the meaning set forth in Section 6.1.

1.81. “**Third Party**” means any Person or entity other than Company, Merck or their respective Affiliates.

1.82. “**Toxicity & Safety Data**” means all clinical adverse event information and/or patient-related safety data included in the Clinical Data, as more fully described in the Pharmacovigilance Agreement.

1.83. “VAT” has the meaning set forth in Section 8.16.

1.84. “**Violation**” means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<http://oig.hhs.gov/exclusions/authorities.asp>); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://exclusions.oig.hhs.gov/>) or listed as having an active exclusion in the System for Award Management (<http://www.sam.gov>); or (c) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) ((a), (b) and (c) collectively the “**Exclusions Lists**”).

2. Scope of the Agreement.

2.1. Generally. Each Party shall: (a) contribute to the Study such resources as are necessary to fulfill its obligations set forth in this Agreement; and (b) act in good faith in performing its obligations under this Agreement and each Related Agreement to which it is a Party.

2.2. Manufacturing Delay. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound as contemplated by this Agreement.

2.3. Compound Commitments.

2.3.1. Company agrees to Manufacture and supply the Company Compound for purposes of the Study in accordance with Article 8, and Company hereby represents and warrants to Merck that, at the time of Delivery of the Company Compound, such Company Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Company Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections.

2.3.2. Merck agrees to Manufacture and supply the Merck Compound for purposes of the Study in accordance with Article 8, and Merck hereby represents and warrants to Company that, at the time of Delivery of the Merck Compound, such Merck Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Merck Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections.

2.3.3. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (*provided* that, for clarity, Company shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 3.4).

2.4. Delegation of Obligations. Each Party shall have the right to delegate any portion of its obligations hereunder as follows: (a) to such Party's Affiliates; (b) to Third Parties that are set forth in the Protocol as performing Study activities or as conducting Sample Testing for such Party; (c) to the extent related to the Manufacture of such Party's Compound; and (d) upon the other Party's prior written consent. Any and all Third Parties to whom a Party delegates any of its obligations hereunder are referred to as "**Subcontractors**". Notwithstanding any delegation of its obligations hereunder, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors to which such Party delegates the performance of its obligations under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement, including the Appendices and Schedules attached hereto. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement.

2.5. Compounds. This Agreement does not create any obligation on the part of Merck to provide the Merck Compound for any activities other than the Study, nor does it create any obligation on the part of Company to provide the Company Compound for any activities other than the Study.

3. Conduct of the Study.

3.1. Sponsor. Company shall act as the sponsor of the Study under its existing IND for the Company Compound with a Right of Reference to the IND of the Merck Compound, as necessary, as further described in Section 3.4; *provided, however*, that in no event shall Company file an additional IND for the Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests an additional IND for the Study the Parties shall meet and mutually agree on an approach to address such requirement.

3.2. Performance. Company shall ensure that the Study is performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP.

3.3. Debarred Personnel; Exclusions Lists. Notwithstanding anything to the contrary contained herein, Company shall not employ or subcontract with any Person that is excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs for the performance of the Study or any other activities under this Agreement or the Related Agreements. Company hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Study or other activities under this Agreement or the Related Agreements and that Company has, as of the Effective Date, screened itself, and its officers and directors, against the Exclusions Lists and that it has informed Merck whether it or any of its officers or directors has been in Violation. Company shall notify Merck in writing immediately if any such suspension, proposed debarment, debarment or Violation occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment, debarred or in Violation, promptly remove such Person from performing in any capacity related to the Study or otherwise related to activities under this Agreement or the Related Agreements.

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3.4. Regulatory Matters. Company shall: (a) obtain, prior to initiating the Study, all Regulatory Approvals from all Regulatory Authorities, ethics committees and/or institutional review boards with jurisdiction over the Study prior to initiating the Study; and (b) follow all directions from any such Regulatory Authorities, ethics committees and/or institutional review boards. Merck shall have the right (but not the obligation) to participate in any discussions with a Regulatory Authority regarding matters related to the Merck Compound. If a Right of Reference is necessary, each Party shall provide to the other a cross-reference letter or similar communication to the applicable Regulatory Authority if needed to effectuate the Right of Reference. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to such other Party's Compound. Merck shall authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Merck Compound INDs and CTAs to provide data access to Company sufficient to support conduct of the Study. If Merck's CTA is not available in a given country, Merck will file its CMC data with the Regulatory Authority for such country, referencing Company's CTA as appropriate ([****]).

3.5. Documentation. Company shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Company shall provide to Merck all Study information and documentation reasonably requested by Merck to enable Merck to (a) comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to the Merck Compound and (b) determine whether the Study has been performed in accordance with this Agreement.

3.6. Copies. Company shall provide to Merck copies of all Clinical Data, in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing and Sample Testing Schedule (if applicable) or upon mutually agreeable timelines; *provided, however*, that a complete copy of the Clinical Data shall be provided to Merck no later than forty-five (45) days following Study Completion. Company shall ensure that all patient authorizations and consents required under HIPAA, the EU Data Protection Directive or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Merck.

3.7. Sample Testing.

3.7.1. Company shall provide Samples to Merck as specified in the Protocol or as agreed to by the Joint Development Committee. Each Party shall (a) use the Samples only for the Sample Testing and (b) conduct the Sample Testing solely in accordance with the Data Sharing and Sample Testing Schedule and the Protocol.

3.7.2. Merck shall own all Sample Testing Results arising from Sample Testing performed by or on behalf of Merck. Solely to the extent specified on the Data Sharing and Sample Testing Schedule as being shared, Merck shall provide to Company the Sample Testing Results for the Sample Testing conducted by or on behalf of Merck, in electronic form or other mutually agreeable alternate form, on the timelines specified in the Data Sharing and Sample Testing Schedule or as otherwise mutually agreed.

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3.7.3. Company shall own all Sample Testing Results arising from Sample Testing performed by or on behalf of Company. Solely to the extent specified on the Data Sharing and Sample Testing Schedule as being shared, Company shall provide to Merck the Sample Testing Results for the Sample Testing conducted by or on behalf of Company, in electronic form or other mutually agreeable alternate form, on the timelines specified in the Data Sharing and Sample Testing Schedule or as otherwise mutually agreed.

3.7.4. Except to the extent otherwise agreed in a writing signed by authorized representatives of each Party, each Party may use and disclose the Sample Testing Results owned by the other Party and shared by such other Party in accordance with the Data Sharing and Sample Testing Schedule solely for the purposes of [****].

3.8. Ownership and Use of Clinical Data.

3.8.1. [****] Company shall maintain the Clinical Data in its internal database; *provided, however*, that at all times during the Term, Company shall grant Merck access to all Clinical Data.

3.8.2. Notwithstanding the foregoing, before publication of the Clinical Data in accordance with Article 12[****]; *provided, however*, that the foregoing shall not limit or restrict either Party's ability to (i) use or disclose the Clinical Data as may be necessary to comply with Applicable Law or with such Party's internal policies and procedures with respect to pharmacovigilance and adverse event reporting or (ii) share with Third Parties or Affiliates Toxicity and Safety Data where because of severity, frequency or lack of reversibility either Party needs to use such Toxicity and Safety Data with respect to its own Compound or the Combination to ensure patient safety.

3.9. Regulatory Submission. It is understood and acknowledged by the Parties that positive Clinical Data could be used to obtain label changes for the Compounds, and each Party may propose a Subsequent Study (as defined below) in connection therewith in accordance with Section 3.14.

3.10. Joint Development Committee; Alliance Managers.

3.10.1. The Parties shall form a joint development committee (the "**Joint Development Committee**" or "**JDC**") made up of an equal number of representatives of Merck and Company, which shall have responsibility for coordinating all regulatory and other activities under, and pursuant to, this Agreement. The JDC will review and finalize the Protocol in accordance with Section 4.1. Each Party shall designate a project manager (the "**Project Manager**") who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties with respect to the Study and shall be a member of the JDC. Other JDC members will be agreed by both Parties.

3.10.2. The JDC shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably considered necessary at the request of either Party, to provide an update on the progress of the Study. The JDC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications equipment. Prior to any such meeting, Company's Project Manager shall provide an update in writing to Merck's Project Manager, which update shall contain information about the overall progress of the Study, recruitment status, interim analysis (if results available), final analysis and other information relevant to the conduct of the Study.

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3.10.3. In addition to a Project Manager, each Party shall designate an alliance manager (the “**Alliance Manager**”), who shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and shall serve as the primary point of contact for any issues arising under this Agreement. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matters or issues either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree in writing. In the event that an issue arises and the Alliance Managers cannot or do not, after good faith efforts, reach agreement on such issue, or if there is a decision to be made by the JDC on which the members of the JDC cannot unanimously agree, the issue shall be elevated to the Vice President of Clinical Oncology for Merck and the Chief Clinical and Regulatory Officer for Company. In the event such escalation does not result in resolution or consensus: (a) Merck shall have final decision-making authority with respect to issues related to Merck Compound; and (b) Company shall have final decision-making authority with respect to issues related to Company Compound.

3.11. *Final Study Report*. Company shall provide Merck with an electronic draft of the final study report promptly following Study Completion, and Merck shall have [****] days after receipt of such draft to provide comments thereon. Company shall consider in good faith any comments provided by Merck on the draft final study report and shall not include any statements relating to the Merck Compound that have not been approved by Merck. Company shall deliver to Merck a final version of the final study report promptly following finalization thereof (the “**Final Study Report**”). “**Study Completion**” shall occur upon database lock of the Study results.

3.12. *Relationship*. Except as expressly set forth in this Agreement, nothing in this Agreement shall: (a) prohibit either Party from performing clinical studies other than the Study relating to its own Compound, either individually or in combination with any other compound or product, in any therapeutic area; or (b) create an exclusive relationship between the Parties with respect to any Compound. Each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, including Company Class Compound or PD-1 Antagonists, *provided* that the Clinical Data, Confidential Information, Jointly Owned Inventions and Sample Testing Results are not used or disclosed in connection therewith in violation of this Agreement.

3.13. *Licensing*. Nothing in this Agreement shall prohibit or restrict a Party from licensing, assigning or otherwise transferring to an Affiliate or Third Party such Party’s Compound or any Inventions, Confidential Information or Sample Testing Results owned solely by such Party. A Party may license, assign or transfer to an Affiliate or Third Party such Party’s interest in the Clinical Data, Confidential Information owned jointly by the Parties and/or Jointly Owned Inventions, and in connection therewith share the shared Sample Testing Results owned by the other Party, solely to the extent such licensee, assignee or transferee agrees in writing to be bound by the terms of this Agreement with respect to such Clinical Data, Confidential Information, Jointly Owned Inventions, and shared Sample Testing Results. For purposes of clarity, any assignment or transfer of this Agreement must comply with Article 18 of this Agreement.

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3.14. Subsequent Study.

3.14.1 During the Term and for a period of [****] months thereafter, either Party shall have the option to propose amending this Agreement and the Related Agreements or negotiating a new agreement (a “**Subsequent Study Agreement**”), as appropriate, for the purpose of conducting a registration study for the Combination in the same indication as the Study (each a “**Subsequent Study**”) by sending a written proposal to the other Party. Company must offer Merck the option of participating in a Subsequent Study prior to entering into an agreement with a Third Party to conduct a registration study in the same indication and line of therapy as the Study of the Company Compound in concomitant and/or sequential administration with a PD-1 Antagonist.

3.14.2 If the receiving Party desires to engage in discussions around the proposed Subsequent Study, such Party shall notify the other Party, in writing, no later than [****] days after receipt of the written proposal. [****]

4. Protocol and Informed Consent: Certain Covenants.

4.1. Protocol. A synopsis of the initial Protocol and the draft statistical analysis plan for the Study have been agreed to by the Parties as of the Effective Date and are attached hereto as Appendix A. Through the JDC, Company shall (a) provide a draft of the Protocol (and any subsequent revisions thereof) to Merck for Merck’s review and comment, (b) consider in good faith any changes to the draft of the Protocol requested by Merck, and (c) incorporate any changes requested by Merck with respect to Merck Compound. Company shall submit the draft Protocol to the JDC for final approval, and the JDC shall promptly review the Protocol and vote on approval thereof. To the extent the JDC cannot agree unanimously regarding the contents of the Protocol for final approval within [****] days of receipt of the Protocol: (i) Company shall have final decision-making authority with respect to matters in the Protocol related to the Company Compound; (ii) Merck shall have final decision-making authority with respect to matters in the Protocol related to [****]; and (iii) all other matters in respect of the Protocol on which the JDC cannot agree shall be resolved in accordance with Section 3.10.3. Once the final Protocol has been approved in accordance with this Section 4.1, any material changes to such approved final Protocol (other than material changes relating solely to the Company Compound) and any changes to the final Protocol (whether or not material) relating to the Merck Compound shall require Merck’s prior written consent. Any such proposed changes will be sent in writing to Merck’s Project Manager and Merck’s Alliance Manager. Merck shall review promptly any such proposed changes to the Protocol.

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4.1.1. Notwithstanding anything to the contrary contained herein, Merck, in its sole discretion, shall have the sole right to determine the dose and dosing regimen for the Merck Compound and shall have the final decision on all matters relating to the Merck Compound (including quantities of Merck Compound to be supplied pursuant to Article 8) and any information regarding the Merck Compound included in the Protocol.

4.1.2. Notwithstanding anything to the contrary contained herein, Company, in its sole discretion, shall have the sole right to determine the dose and dosing regimen for the Company Compound and shall have the final decision on all matters relating to the Company Compound (including quantities of Company Compound to be supplied pursuant to Article 8) and any information regarding the Company Compound included in the Protocol.

4.2. Informed Consent. Company shall prepare the patient informed consent form for the Study (which shall include provisions regarding the use of Samples in Sample Testing) in consultation with Merck (it being understood and agreed that the portion of the informed consent form relating to the Sample Testing of the Merck Compound shall be provided to Company by Merck). Any proposed changes to such form that relate to the Merck Compound, including Sample Testing of the Merck Compound, shall be subject to Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [****] Business Days after Merck receives a copy of Company's requested changes.

4.3. Financial Disclosure. Company shall (a) track and collect financial disclosure information from all "clinical investigators" involved in the Study and (b) prepare and submit the certification and/or disclosure of the same in accordance with all Applicable Law, including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Prior to the initiation of clinical activities under the Study, but in any event within [****] days after the Effective Date, the Parties shall determine whether Company shall track and collect from all "clinical investigators" involved in the Study separate certification and/or disclosure forms for each of Merck and Company or one (1) "combined" certification and/or disclosure form for both Merck and Company. For purposes of this Section 4.3, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

4.4. Transparency Reporting. Each Party shall be responsible for reporting payments and other transfers of value made to health care professionals, including, without limitation, investigators, steering committee members, data monitoring committee members, and consultants in connection with the Study in accordance with reporting requirements under Applicable Law, including, without limitation, the Physician Payment Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and such Party's applicable policies; *provided, however*, if Company will not be required to make a transparency report under Applicable Law for any annual reporting period thereunder, Company shall notify Merck in writing of such status within [****] calendar days after the commencement of such reporting period, and during such reporting period the Company shall track and provide to Merck data regarding "indirect" payments or other transfers of value by Company to such health care professionals to the extent such payments or other transfers of value were required, instructed, directed or otherwise caused by Merck pursuant to this Agreement. The data will be in a format requested by Merck and provided on a basis to be agreed upon by both Parties. Company represents and warrants that the information so provided will be complete and accurate to the best of its knowledge.

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5. Adverse Event Reporting.

5.1. Pharmacovigilance Agreement. Company will be solely responsible for compliance with all Applicable Laws pertaining to safety reporting for the Study and related activities. The Parties (or their respective Affiliates) will execute a pharmacovigilance agreement (the “**Pharmacovigilance Agreement**”) prior to the initiation of clinical activities under the Study, but in any event within [****] days after the Effective Date, to ensure the exchange of relevant safety data within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall control. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Merck Compound and Company Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Government Authorities.

5.2. Transmission of SAEs. Company will transmit to Merck all serious adverse events (“SAEs”) as follows:

5.2.1. For drug-related fatal and life-threatening SAEs, Company will send a processed case (on a CIOMS-1 form in English) within [****] calendar days after receipt by Company of such SAEs.

5.2.2. For all other SAEs, including non-drug-related fatal and life-threatening SAEs, Company will send a processed case (on a CIOMS-1 form in English) within [****] calendar days after receipt by Company of such SAEs.

6. Term and Termination.

6.1. Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until delivery of the Final Study Report, unless terminated earlier by either Party pursuant to this Article 6 (the “**Term**”).

6.2. Merck Termination for Safety. In the event that Merck in good faith believes that the Merck Compound is being used in the Study in an unsafe manner and notifies Company in writing of the grounds for such belief, and Company fails to promptly incorporate changes into the Protocol requested by Merck to address such issue or to otherwise address such issue reasonably and in good faith, Merck may terminate this Agreement and the supply of the Merck Compound immediately upon written notice to Company.

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6.3. *Termination for Material Breach.* Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for [****] days after receipt of written notice thereof from the non-breaching Party; *provided* that if such material breach cannot reasonably be cured within [****] days, the breaching Party shall be given a reasonable period of time to cure such breach; *provided further*, that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement effective after the expiration of such [****] day period.

6.4. *Termination for Patient Safety.* If either Party determines in good faith, based on a review of the Clinical Data, Sample Testing Results or other Study-related Know-How or other information, that the Study may unreasonably affect patient safety, such Party shall promptly notify the other Party of such determination. The Party receiving such notice may propose modifications to the Study to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to implement immediately such modifications; *provided, however*, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the other Party to propose modifications and may instead terminate this Agreement immediately upon written notice to such other Party. Furthermore, if the notifying Party, in its sole discretion, believes that any modifications proposed by the other Party will not resolve the patient safety issue, such Party may terminate this Agreement effective upon written notice to such other Party.

6.5. *Termination for Regulatory Action; Other Reasons.* Either Party may terminate this Agreement immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the Study. Additionally, either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound, for medical, scientific or legal reasons.

6.6. *Termination related to Anti-Corruption Obligations.* Either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform any of its obligations under Section 13.4 or breaches any representation or warranty contained in Section 13.4. Except as set forth in Section 6.11, the non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.6.

6.7. *Return of Merck Compound.* In the event that this Agreement is terminated, or in the event Company remains in possession (including through any Affiliate or Subcontractor) of Merck Compound at the time this Agreement expires, Company shall, at Merck's sole discretion, promptly either return or destroy all unused Merck Compound pursuant to Merck's instructions. If Merck requests that Company destroy the unused Merck Compound, Company shall provide written certification of such destruction.

6.8. *Survival.* The provisions of Sections 3.4 through 3.9 (inclusive), 3.14, 5, 6.7 through 6.11 (inclusive), 8.5.2, 8.11, 8.14 through 8.16 (inclusive), 12.2, 13.4.6, 14.2, and 14.3, and Articles 1, 5, 9 through 12 (inclusive), 17, and 20 through 25 (inclusive) shall survive the expiration or termination of this Agreement.

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6.9. *No Prejudice*. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

6.10. *Confidential Information*. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Inventions) furnished to the Receiving Party by the Disclosing Party; *provided, however* that the Receiving Party may retain one copy of such Confidential Information in its confidential files, solely for purposes of exercising the Receiving Party's rights hereunder, satisfying its obligations hereunder or complying with any legal proceeding or requirement with respect thereto, and *provided further* that the Receiving Party shall not be required to erase electronic files created in the ordinary course of business during automatic system back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information so long as such electronic files are (a) maintained only on centralized storage servers (and not on personal computers or devices), (b) not accessible by any of its personnel (other than its information technology specialists), and (c) are not otherwise accessed subsequently except with the written consent of the Disclosing Party or as required by law or legal process. Such retained copies of Confidential Information shall remain subject to the confidentiality and non-use obligations herein.

6.11. *Manufacturing Costs*. In the event of termination by Merck pursuant to Section 6.2, 6.3 or 6.6 above, Merck shall be entitled to [****] (as defined herein) incurred by Merck for its Compound Delivered for the Study. [****]

7. Costs of Study.

The Parties agree that: (a) Merck shall provide the Merck Compound for use in the Study, as described in Article 8 below; (b) each Party will be responsible for its own internal costs and expenses to support the Study and the costs of any Sample Testing conducted by such Party in connection with the Study; and (c) Company shall bear all other costs associated with the conduct of the Study, including that Company shall provide the Company Compound for use in the Study, as described in Article 8 below. For the avoidance of doubt, Company will not be required to reimburse Merck for any costs or expenses incurred by Merck or its Affiliates in connection with the Study (except as provided in Section 6.11) and Merck will not be required to reimburse Company for any costs or expenses incurred by Company or its Affiliates in connection with the Study (except as provided in Section 6.11).

8. Supply and Use of the Compounds.

8.1. *Supply of the Compounds*. Subject to the terms and conditions of this Agreement, each of Company and Merck will use commercially reasonable efforts to supply, or cause to be supplied, the quantities of its respective Compound as are set forth in Appendix B, on the timelines set forth in Appendix B, in each case for use in the Study. If the Protocol is changed in accordance with Article 4 in such a manner that may affect the quantities of Compound to be provided or the timing for providing such quantities, the Parties shall amend Appendix B to reflect any changes required to be consistent with the Protocol. Each Party shall also provide to the other Party a contact person for the supply of its Compound under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, in the event that a Party is: (a) not supplying its Compound in accordance with the terms of this Agreement, then the other Party shall have no obligation to supply its Compound; or (b) allocating under Section 8.10 then the other Party may allocate proportionally.

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8.2. Clinical Quality Agreement. Within [*****] days after the Effective Date of this Agreement, but in any event before any supply of Merck Compound hereunder, the Parties (or their respective Affiliates) shall enter into a quality agreement that shall address and govern issues related to the quality of clinical drug supply to be supplied by the Parties for use in the Study (the “**Clinical Quality Agreement**”). In the event of any inconsistency between the terms of this Agreement and the Clinical Quality Agreement, the terms of this Agreement shall control. The Clinical Quality Agreement shall, among other things: (a) detail classification of any Compound found to have a Non-Conformance; (b) include criteria for Manufacturer’s Release and related certificates and documentation; (c) include criteria and timeframes for acceptance of Merck Compound; (d) include procedures for the resolution of disputes regarding any Compounds found to have a Non-Conformance; and (e) include provisions governing the recall of Compounds.

8.3. Minimum Shelf Life Requirements. Each Party shall use commercially reasonable efforts to supply its Compound hereunder with reasonable remaining shelf life at the time of Delivery to meet the Study requirements.

8.4. Provision of Compounds.

8.4.1. Merck will deliver the Merck Compound DAP (INCOTERMS 2010) to Company’s, or its designee’s, location as specified by Company (“**Delivery**” with respect to such Merck Compound). Title and risk of loss for the Merck Compound shall transfer from Merck to Company at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Merck Compound shall be borne by Company. Company will, or will cause its designee to: (a) take delivery of the Merck Compound supplied hereunder; (b) perform the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement; (c) subsequently label and pack the Merck Compound (in accordance with Section 8.5); and promptly ship the Merck Compound to the Study sites for use in the Study, in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement; and (d) provide, from time to time at the reasonable request of Merck, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Merck, and usage and inventory reconciliation documentation related to the Merck Compound.

8.4.2. Company is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Company Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the Company Compound supplied hereunder. Company shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement. For purposes of this Agreement, the “**Delivery**” of a given quantity of the Company Compound shall be deemed to occur when such quantity is packaged for shipment to a Study site.

8.5. Labeling and Packaging; Use, Handling and Storage.

8.5.1. The Parties' obligations with respect to the labeling and packaging of the Compounds are as set forth in the Clinical Quality Agreement. Notwithstanding the foregoing or anything to the contrary contained herein, Merck shall provide the Merck Compound to Company in the form of unlabeled vials, and Company shall be responsible for labeling, packaging and leafletting such Merck Compound in accordance with the terms and conditions of the Clinical Quality Agreement and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.

8.5.2. Company shall: (a) use the Merck Compound solely for purposes of performing the Study; (b) not use the Merck Compound in any manner that is inconsistent with this Agreement or for any commercial purpose; and (c) label, use, store, transport, handle and dispose of the Merck Compound in compliance with Applicable Law and the Clinical Quality Agreement, as well as all written instructions of Merck pertaining to the Merck Compound. Company shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Merck Compound, and in particular shall not analyze the Merck Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Quality Agreement.

8.6. Product Specifications. A certificate of analysis, Material Safety Data Sheet, and all storage and handling information shall accompany each shipment of the Merck Compound to Company. Upon request, Company shall provide Merck with a certificate of analysis covering each shipment of Company Compound used in the Study.

8.7. Changes to Manufacturing. Each Party may make changes from time to time to its Compound or the Manufacturing Site, *provided* that such changes shall be in accordance with the Clinical Quality Agreement.

8.8. Product Testing; Noncompliance.

8.8.1. *After Manufacturer's Release.* After Manufacturer's Release of the Merck Compound and concurrently with Delivery of the Compound to Company, Merck shall provide Company with such certificates and documentation as are described in the Clinical Quality Agreement ("**Disposition Package**"). Company shall, within the time defined in the Clinical Quality Agreement, perform, with respect to the Merck Compound, the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement. Company shall be solely responsible for taking all steps necessary to determine that Merck Compound or Company Compound, as applicable, is suitable for release before making such Merck Compound or Company Compound, as applicable, available for human use, and Merck shall provide cooperation or assistance as reasonably requested by Company in connection with such determination with respect to the Merck Compound. Company shall be responsible for storage and maintenance of the Merck Compound until it is tested and/or released, which storage and maintenance shall be in compliance with (a) the Specifications for the Merck Compound, the Clinical Quality Agreement and Applicable Law and (b) any specific storage and maintenance requirements as may be provided by Merck from time to time. Company shall be responsible for any failure of the Merck Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to Company hereunder.

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8.8.2. *Non-Conformance.*

(a) In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.8.1), such Party shall immediately notify the other Party in accordance with the procedures of the Clinical Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 (Investigations) and any discrepancy between them shall be resolved in accordance with Section 8.8.3.

(b) In the event that any proposed or actual shipment of the Merck Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Company, then unless otherwise agreed to by the Parties, Merck shall replace such Merck Compound as is found to have a Non-Conformance (with respect to Merck Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Company with respect to any Merck Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) [****], (ii) [****] and (iii) [****]; *provided* that, for clarity, Company shall not be deemed to be waiving any rights under Section 8.15. In the event Merck Compound is lost or damaged by Company after Delivery, Merck shall provide additional Merck Compound (if available for the Study) to Company; *provided* that Company shall [****]. Except as set forth in the foregoing sentence, Merck shall have no obligation to provide replacement Merck Compound for any Merck Compound supplied hereunder other than such Merck Compound as has been agreed or determined to have a Non-Conformance at the time of Delivery to Company.

(c) Company shall be responsible for, and Merck shall have no obligation or liability with respect to, any Company Compound supplied hereunder that is found to have a Non-Conformance. Company shall replace any Company Compound as is found to have a Non-Conformance (with respect to Company Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Merck with respect to any Company Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) [****], (ii) [****], and (iii) termination of this Agreement pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein); *provided* that, for clarity, Merck shall not be deemed to be waiving any rights under Section 8.15.

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8.8.3. *Resolution of Discrepancies.* Disagreements regarding any determination of Non-Conformance by Company shall be resolved in accordance with the provisions of the Clinical Quality Agreement.

8.9. *Investigations.* The process for investigations of any Non-Conformance shall be handled in accordance with the Clinical Quality Agreement.

8.10. *Shortage: Allocation.* In the event that a Party's Compound is in short supply such that a Party reasonably believes in good faith that it will not be able to fulfill its supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply) and the Parties will promptly discuss such situation (including how the quantity of Compound that such Party is able to supply hereunder will be allocated within the Study). In such event, the Party experiencing such shortage shall (i) use its commercially reasonable efforts to remedy the situation giving rise to such shortage and to take action to minimize the impact of the shortage on the Study, and (ii) [****].

8.11. *Records: Audit Rights.* Company shall keep complete and accurate records pertaining to its use and disposition of Merck Compound (including its storage, shipping (cold chain) and chain of custody activities) and, upon request of Merck, shall make such records open to review by Merck for the purpose of conducting investigations for the determination of Merck Compound safety and/or efficacy and Company's compliance with this Agreement with respect to the Merck Compound.

8.12. *Quality.* Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement.

8.13. *Quality Control.* Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the Clinical Quality Agreement.

8.14. *Audits and Inspections.* The Parties' audit and inspection rights related to this Agreement shall be governed by the terms of the Clinical Quality Agreement.

8.15. *Recalls.* Recalls of the Compounds shall be governed by the terms of the Clinical Quality Agreement.

8.16. *VAT.*

(a) It is understood and agreed between the Parties that any payments made and any other consideration given under this Agreement are each exclusive of any value added or similar tax ("VAT"), which shall be added thereon as applicable and at the relevant rate. Subject to Section 8.16(b), where VAT is properly charged by the supplying Party and added to a payment made or other consideration provided (as applicable) under this Agreement, the Party making the payment or providing the other consideration (as applicable) will pay the amount of VAT properly chargeable only on receipt of a valid tax invoice from the supplying Party issued in accordance with the laws and regulations of the country in which the VAT is chargeable. Each Party agrees that it shall provide to the other Party any information and copies of any documents within its Control to the extent reasonably requested by the other Party for the purposes of (i) determining the amount of VAT chargeable on any supply made under this Agreement, (ii) establishing the place of supply for VAT purposes, or (iii) complying with its VAT reporting or accounting obligations.

(b) Where one Party or its Affiliate (the “**First Party**”) is treated as making supply of goods or services in a particular jurisdiction (for VAT purposes) for no consideration, and the other Party or its Affiliate (the “**Second Party**”) is treated as receiving such supply in the same jurisdiction, thus resulting in an amount of VAT being properly chargeable on such supply, the Second Party shall only be obliged to pay to the First Party the amount of VAT properly chargeable on such supply (and no other amount). The Second Party shall pay such VAT to the First Party on receipt of a valid VAT invoice from the First Party (issued in accordance with the laws and regulations of the jurisdiction in which the VAT is properly chargeable). Each Party agrees to (i) use its reasonable efforts to determine and agree the value of the supply that has been made and, as a result, the corresponding amount of VAT that is properly chargeable and (ii) provide to the other Party any information or copies of documents in its Control as are reasonably necessary to evidence that such supply will take, or has taken, place in the same jurisdiction (for VAT purposes).

9. Confidentiality.

9.1. Confidential Information. Subject to Section 13.4.8, Company and Merck agree to hold in confidence any Confidential Information provided by or on behalf of the other Party, and neither Party shall use Confidential Information of the other Party except to fulfill such Party’s obligations under this Agreement or exercising its rights. Without limiting the foregoing, the Receiving Party may not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) *provided* that the Receiving Party shall provide reasonable advance notice to the Disclosing Party before making such disclosure. For the avoidance of doubt, Company may, without Merck’s consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing the Study, the data safety monitoring and advisory board relating to the Study, and Regulatory Authorities working with Company on the Study, in each case to the extent necessary for the performance of the Study and *provided* that such Persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein.

9.2. Inventions. Notwithstanding the foregoing: (i) Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12; and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12.

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9.3. *Personal Identifiable Data.* All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such data.

10. *Intellectual Property.*

10.1. *Joint Ownership and Prosecution.*

10.1.1. All rights to all Inventions relating to, or covering, [****] (each a “**Jointly Owned Invention**”) shall be owned jointly by Company and Merck. Merck hereby assigns to Company an undivided one-half interest in, to and under the Jointly Owned Inventions that are invented or created solely by Merck or by Persons having an obligation to assign such rights to Merck. Company hereby assigns to Merck an undivided one-half interest in, to and under any Jointly Owned Inventions that are invented or created solely by Company or by Persons having an obligation to assign such rights to Company. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention to practice such Jointly Owned Invention in such countries: (a) Merck hereby grants to Company a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Merck’s right, title and interest in and to all Jointly Owned Inventions to use such Inventions in accordance with the terms of this Agreement; and (b) Company hereby grants to Merck a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Company’s right, title and interest in and to all Jointly Owned Inventions to use such Inventions in accordance with the terms of this Agreement. For clarity, the terms of this Agreement do not provide Company or Merck with any rights, title or interest or any license to the other Party’s intellectual property except as necessary to conduct the Study and as expressly provided under this Agreement, including as set forth in Section 10.4.

10.1.2. Each Party shall have the right to [****].

10.1.3. Promptly following the Effective Date, but in any event as soon as practicable after the discovery of a Jointly Owned Invention, patent representatives of each of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions that may arise. In particular, the Parties shall discuss which Party will file and prosecute a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of any Jointly Owned Invention (each, a “**Joint Patent Application**”) and whether the Parties wish to appoint counsel that is mutually acceptable to the Parties. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of such patent application and shall equally share the expenses associated with the Joint Patent Applications and any corresponding Joint Patents. In the event that one Party (the “**Filing Party**”) wishes to file a patent application for a Jointly Owned Invention and the other Party (the “**Non-Filing Party**”) does not want to file a patent application for such Jointly Owned Invention or does not want to file in a particular country, the Non-Filing Party shall execute in a timely manner and at the Filing Party’s reasonable expense an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) and any additional documents as may be reasonably necessary to allow the Filing Party to file and prosecute such patent application. If a Party (the “**Opting-out Party**”) wishes to discontinue the prosecution and maintenance (or sharing in the costs with respect thereto) of a Joint Patent Application or Joint Patent (in one or more countries), the other Party, at its sole option (the “**Continuing Party**”), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute in a timely manner and at the Continuing Party’s reasonable expense an assignment of such Joint Patent Application or Joint Patent to the Continuing Party (in such country or all countries, as applicable) and any additional documents as may be necessary to allow the Continuing Party to prosecute and maintain such Joint Patent Application or Joint Patent. Any Jointly Owned Invention, Joint Patent Application or Joint Patent so assigned shall thereafter be owned solely by the Continuing Party or Filing Party (as applicable), shall no longer be considered jointly owned, and the Non-Filing Party or Opting-out Party (as applicable) shall have no right to practice under such Joint Patent Application or Joint Patent in the applicable country or countries.

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10.1.4. Except as expressly provided in Section 10.1.3 and in furtherance and not in limitation of Section 9.1, each Party agrees to make no patent application based on the other Party's Confidential Information, and to give no assistance to any Third Party for such application, without the other Party's prior written authorization.

10.1.5. Company shall have the first right to initiate legal action to enforce all Joint Patents against infringement and to protect all Jointly Owned Inventions from misappropriation by any Third Party, where [****] or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that Company fails to initiate or defend such action within thirty (30) days after being first notified of such infringement, Merck shall have the right to do so at its sole expense. Merck shall have the first right to initiate legal action to enforce all Joint Patents against infringement and to protect all Jointly Owned Inventions from misappropriation by any Third Party, where [****] or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that Merck fails to initiate or defend such action within thirty (30) days after being first notified of such infringement, Company shall have the right to do so at its sole expense. The Parties shall cooperate in good faith to coordinate legal action to enforce all Joint Patents against infringement, and to protect all Jointly Owned Inventions from misappropriation, by any Third Party where [****] or to defend any declaratory judgment action relating thereto, and shall share the costs and expenses of such litigation equally. Any damages or other monetary awards recovered shall be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action shall be first applied to the out-of-pocket costs of each Party in connection with such action; and then (b) any remaining proceeds shall be divided evenly between Company and Merck.

10.1.6. If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any Joint Patent, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit. The costs and expenses of the Party bringing suit under this Section 10.1.6 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action shall be first applied to the out-of-pocket costs of each Party in connection with such action; and then (b) any remaining proceeds shall be divided evenly between Company and Merck. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.1.6 may not be entered into without the consent of the Party not bringing the suit.

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10.2. *Inventions Owned by Company.* Notwithstanding anything to the contrary contained in Section 10.1, the Parties agree that all rights to Inventions relating [****], or covering [****], regardless of whether such Invention or improvement was invented solely by Company or Merck or jointly by the Parties, are the exclusive property of Company (“**Company Inventions**”). Company shall be entitled to file and prosecute in its own name relevant patent applications and to own resultant patent rights for any Company Invention. For the avoidance of doubt, any Invention [****], is a Company Invention. Merck hereby assigns its right, title and interest to any and all Company Inventions to Company.

10.3. *Inventions Owned by Merck.* Notwithstanding anything to the contrary contained in Section 10.1, the Parties agree that all rights to Inventions relating [****], or covering [****], regardless of whether such Invention or improvement was invented solely by Merck or Company or jointly by the Parties, are the exclusive property of Merck (“**Merck Inventions**”). Merck shall be entitled to file and prosecute in its own name relevant patent applications and to own resultant patent rights for any Merck Invention. For the avoidance of doubt, any Invention [****], even where [****], is a Merck Invention. Company hereby assigns its right, title and interest to any and all Merck Inventions to Merck.

10.4. *Mutual Freedom to Operate for Combination Inventions.*

10.4.1. *Company License to Merck.* Company hereby grants to Merck a non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license to any patent Controlled by Company, including composition of matter and method patents, that [****] (the “**Company Background Patents**”) solely for [****]; *provided, however*, that in no event shall Merck have the right to use Company Background Patents to commercialize the Company Compound or any Company Class Compound.

10.4.2. *Merck License to Company.* Merck hereby grants to Company a non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license to any patent Controlled by Merck that [****] (the “**Merck Background Patents**”) solely for [****]; *provided, however*, that in no event shall Company have the right to use Merck Background Patents to commercialize the Merck Compound or any PD-1 Antagonist.

10.4.3. *No Other Rights.* For clarity, the terms of this Section 10.4 do not provide Merck or Company with any rights, title or interest or any license to the other Party’s intellectual property rights which [****].

10.4.4. *Termination.* Any and all licenses granted under this Section 10.4 shall terminate upon the expiration or earlier termination of this Agreement and shall not survive such expiration or termination.

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11. Reprints; Rights of Cross-Reference.

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study that disclose the name of a Party, *provided, however*, that such use does not constitute an endorsement of any commercial product or service by the other Party.

12. Publications; Press Releases.

12.1. Clinical Trial Registry. Company shall register the Study with the Clinical Trials Registry located at www.clinicaltrials.gov and is committed to timely publication of the results following Study Completion, after taking appropriate action to secure intellectual property rights (if any) arising from the Study. The publication of the results of the Study will be in accordance with the Protocol.

12.2. Publication. Each Party shall use reasonable efforts to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of such results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published, presented, or otherwise disseminated according to the following procedure:

12.2.1. At least [****] days prior to submission for publication of any paper, letter or any other publication, or [****] days prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the full details of the proposed publication, presentation, or dissemination in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation/dissemination for an additional [****] days in order to allow for actions to be taken to preserve rights for patent protection.

12.2.2. The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in Section 12.2.1 to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication.

12.2.3. The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.

12.3. Press Releases. Promptly following the Effective Date, Company may issue the press release attached hereto as Appendix C. Unless otherwise required by Applicable Law (including applicable regulations of a stock exchange on which either Party's securities are listed), neither Party shall make any other public announcement concerning this Agreement without the prior written consent of the other Party. To the extent a Party desires to make such public announcement, such Party shall provide the other Party with a draft thereof at least seven (7) Business Days prior to the date on which such Party would like to make the public announcement, unless a shorter time period is required to comply with Applicable Law (including applicable regulations of a stock exchange on which such Party's securities are listed), in which case, the Party intending to make such public announcement shall provide the other Party with as much advance notice as is reasonably practicable.

13. Representations and Warranties; Disclaimers.

13.1. Due Authorization. Each of Company and Merck represents and warrants to the other that: (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

13.2. Compounds.

13.2.1. Company Compound. Company hereby represents and warrants to Merck that: (a) Company has the full right, power and authority to grant all of the licenses granted to Merck under this Agreement; and (b) Company Controls the Company Compound.

13.2.2. Merck Compound. Merck hereby represents and warrants to Company that: (a) Merck has the full right, power and authority to grant all of the licenses granted to Company under this Agreement; and (b) Merck Controls the Merck Compound.

13.3. Results. Company does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Neither Party shall be liable for any use that the other Party may make of the Clinical Data nor for advice or information given in connection therewith.

13.4. Anti-Corruption.

13.4.1. In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Company and Merck and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner that is consistent with all Applicable Law, including the Stark Act, Anti-Kickback Statute, Sunshine Act, and the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies and agrees to abide by the spirit of the other Party's guidelines, which may be provided by such other Party from time to time.

13.4.2. Specifically, each Party represents and warrants that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

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13.4.3. Neither Party shall contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.4.4. Each Party represents and warrants that (a) it is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; and (b) it has not employed or subcontracted with any Person for the performance of the Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs.

13.4.5. Each Party represents and warrants that, except as disclosed to the other in writing prior to the Effective Date, such Party: (a) does not have any interest that conflicts with its proper and ethical performance of this Agreement; (b) shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (c) has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of any due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures to the other Party as are necessary to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that it shall not hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement, *provided* that such hiring or retention shall be subject to the completion by the hiring or retaining Party of a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

13.4.6. Each Party shall have the right during the Term, [****], to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.4. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit.

13.4.7. Each Party shall use commercially reasonable efforts to ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

Confidential Treatment Requested. Omitted Portions are Marked with [**] and have been Filed Separately with the Securities and Exchange Commission.**

13.4.8. Each Party agrees that in the event that the other Party believes in good faith that there has been a possible material violation of any provision of Section 13.4, such other Party may make full disclosure of such belief and related information needed to support such belief at any time and for any reason to any competent government bodies and agencies, and to anyone else such Party determines in good faith has a legitimate need to know.

13.4.9. Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject, and shall conduct its Study-related activities in accordance with Applicable Law. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to his/her performance of any obligations or activities under this Agreement. Each Party shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.

13.4.10. Each Party shall have the right to terminate this Agreement immediately upon violation of this Section 13.4 in accordance with Section 6.6.

13.5. DISCLAIMER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, MERCK MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE MERCK COMPOUND, AND COMPANY MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE COMPANY COMPOUND.

14. Insurance; Indemnification; Limitation of Liability.

14.1. Insurance. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, a Party shall provide evidence of such insurance.

14.2. Indemnification.

14.2.1. Indemnification by Company. Company agrees to defend, indemnify and hold harmless Merck, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of [****] (a "**Liability**"), except to the extent that such Liability [****].

14.2.2. Indemnification by Merck. Merck agrees to defend, indemnify and hold harmless Company, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability to the extent such Liability was directly caused by (a) negligence or willful misconduct on the part of Merck (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (b) a breach on the part of Merck of any of its representations and warranties or any other covenants or obligations of Merck under this Agreement; or (c) a breach of Applicable Law by Merck.

14.2.3. *Procedure*. The obligations of Merck and Company under this Section 14.2 are conditioned upon the delivery of written notice to Merck or Company, as the case might be, of any potential Liability within a reasonable time after a Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; *provided* that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner). The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Party controlling such defense (the “**Defending Party**”) shall keep the other Party (the “**Other Party**”) advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.

14.2.4. *Study Subjects*. Company shall not offer compensation on behalf of Merck to any Study subject or bind Merck to any indemnification obligations in favor of any Study subject. Merck shall not offer compensation on behalf of Company to any Study subject or bind Company to any indemnification obligations in favor of any Study subject.

14.3. LIMITATION OF LIABILITY. IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY UNDER ANY THEORY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES OR ANY PUNITIVE DAMAGES OR ANY LOST PROFIT, LOST SALE OR LOST OPPORTUNITY DAMAGES (WHETHER SUCH CLAIMED DAMAGES ARE DIRECT OR INDIRECT), WHETHER ARISING DIRECTLY OR INDIRECTLY OUT OF (X) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (Y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY’S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT WITH RESPECT TO USE, DISCLOSURE, LICENSE, ASSIGNMENT OR OTHER TRANSFER OF CLINICAL DATA, CONFIDENTIAL INFORMATION, JOINTLY-OWNED INVENTIONS AND SAMPLE TESTING RESULTS.

Confidential Treatment Requested. Omitted Portions are Marked with [**] and have been Filed Separately with the Securities and Exchange Commission.**

15. Use of Name.

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement without the other Party's prior written consent.

16. Force Majeure.

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, fire, strike, acts of terror, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party shall notify the other Party of such Force Majeure within [****] days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

17. Entire Agreement; Amendment; Waiver.

This Agreement, together with the Appendices and Schedules hereto and the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. In the event of a conflict between a Related Agreement and this Agreement, the terms of this Agreement shall control. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

18. Assignment and Affiliates.

Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; *provided, however*, that either Party may assign all or any part of this Agreement to one or more of its Affiliates without the other Party's consent, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, *provided* that such Affiliates agree to be bound by this Agreement.

19. Invalid Provision.

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

20. No Additional Obligations.

Company and Merck have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Study. Nothing in this Agreement obligates the Parties to enter into any other agreement (other than the Related Agreements) at this time or in the future.

21. Governing Law: Dispute Resolution.

21.1. The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles.

21.2. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

22. Notices.

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Company, to:

OncoSec Medical Incorporated
5820 Nancy Ridge Drive
San Diego, CA 92121
Attention: Legal Department
With a copy to:

If to Merck, to:

MSD International GmbH
Weystrasse 20
6000 Luzern 6
Switzerland
Attention:
Facsimile:

With copies (which shall not constitute notice) to:

23. Relationship of the Parties.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, that are binding on the other Party, except with the prior written consent of the other Party to do so. All Persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

24. Counterparts and Due Execution.

This Agreement and any amendment may be executed in any number of counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

25. Construction.

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word “**or**” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “**including**” as used herein shall be deemed to be followed by the phrase “**without limitation**” or like expression. The term “**will**” as used herein means shall. The terms “**hereof**”, “**hereto**”, “**herein**” and “**hereunder**” and words of similar import when used in this Agreement refer to this Agreement as a whole and no to any particular provision of this Agreement. References to “**Article**,” “**Section**”, “**Appendix**” or “**Schedule**” are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this “**Agreement**” shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

OncoSec Medical Incorporated

By: /s/ Punit Dhillon

Punit Dhillon
Name

President and Chief Executive Officer
Title

MSD International GmbH

By: /s/ Franz Escherich

Franz Escherich
Name

Director
Title

Appendix A

PROTOCOL SYNOPSIS

Study Title	The PISCES Study: A Multicenter Phase 2, Open-Label Trial of Intratumoral pIL-12 plus Electroporation in Combination with Intravenous Pembrolizumab in Patients with Stage III/IV Melanoma who are Progressing on either Pembrolizumab or Nivolumab Treatment
Protocol No.	OMS-I103
[*****]	[*****]
Study Phase	2
Therapeutic Indication	Intratumoral injection of plasmid interleukin-12 followed by electroporation (ImmunoPulse® IL-12), in combination with an anti-programmed cell death protein 1 (PD-1) antibody pembrolizumab, is indicated for the treatment of unresectable or metastatic melanoma.
Study Objectives	<ul style="list-style-type: none">• To assess efficacy of best overall response rate (BORR) by independent central review based on RECIST v1.1 over 24 weeks (end of Core study) of intratumoral pIL-12-EP in combination with pembrolizumab (IV) (collectively ‘the combined treatment’) in patients with unresectable or metastatic melanoma who previously have progressed on prior approved anti-PD-1 antibodies (either as monotherapy or in combination with other approved checkpoint inhibitor).• To assess safety and tolerability of the combined treatment in patients with unresectable or metastatic melanoma who previously have progressed on prior approved anti-PD-1 antibodies (either as monotherapy or in combination with other approved checkpoint inhibitor).• To assess duration of response (DOR), objective response rate (ORR), immune BORR (iBORR), progression free survival (PFS), immune PFS (iPFS), and overall survival (OS) of combination therapy;• [*****]
Investigational Product Route and Dosage Form	Plasmid interleukin-12 (pIL-12) will be injected intratumorally (on Days 1, 5 and 8 every 6 weeks) [*****] Pembrolizumab will be administered at a dose of 200 mg [*****]
Study Design	<p>This will be a Phase 2, Simon 2-stage minimax design, non-comparative, open-label, single-arm, multicenter study of intratumoral pIL-12-EP plus IV pembrolizumab. Eligible patients will be those with pathological diagnosis of unresectable or metastatic melanoma who are progressing or have progressed on pembrolizumab or nivolumab (either as monotherapy or in combination with another approved checkpoint inhibitor confirmed according to RECIST v1.1. If a patient is BRAF V600 mutation positive, they must have received a BRAF inhibitor according to the approved label.</p> <p>The study will be comprised of a Core study (24 weeks), an Extension Phase and a long-term follow-up.</p> <p>Core study: Eligible patients will be treated with intratumoral pIL-12-EP to the accessible lesions on Days 1, 5 and 8 every 6 weeks and with IV pembrolizumab (200 mg) [*****] for 24 weeks. [*****]</p> <p>Extension phase: Patients who completed 24 weeks of treatment (Core study) with the investigators discretion, will enter an Extension phase [*****]</p>
Study Duration	The study duration for each individual patient will be 24 weeks in the Core study (excluding the screening period), up to 35 pembrolizumab cycles from baseline (approximately 2 years) in the Extension phase and long-term follow-up (until death, patient withdraw consent or sponsor terminates the study).
Immune Monitoring	For Immune Monitoring, tumor biopsies (fixed and fresh) as well as blood and fecal samples will be collected [*****]
[*****]	[*****]

Confidential Treatment Requested. Omitted Portions are Marked with [***] and have been Filed Separately with the Securities and Exchange Commission.**

Inclusion Criteria

In order to be eligible for participation in this trial, the patient must meet all the following:

1. Pathologically documented unresectable melanoma, AJCC Stage III or IV. Patients must have histological or cytological confirmed diagnosis of unresectable melanoma with progressive locally advanced or metastatic disease.
2. Patients must be refractory to anti-PD-1 monoclonal antibodies (mAb) defined as pembrolizumab or nivolumab as either as monotherapy or in combination with other approved checkpoint inhibitors or targeted therapies according to their approved label, defined as (patients must meet all of the following criteria):
 - a. Received at least 4 doses of anti-PD1 mAb (minimum dose of 2 mg/kg given every three weeks (Q3W) for pembrolizumab; minimum dose of 240 mg given every two weeks (Q2W) for nivolumab in monotherapy; minimum dose of 1 mg/kg given Q3W for nivolumab in combination with ipilimumab
 - b. Progressive disease after anti-PD1 mAb will be defined according to RECIST v1.1. [*****]
 - c. Documented disease progression within 24 weeks of the last dose of anti-PD1 mAb. Patients who were re-treated with anti-PD1 mAb and patients who were on maintenance with anti-PD1 mAb will be allowed to enter the trial as long as there is documented PD within 24 weeks of the last treatment date (with anti-PD1 mAb).
3. Resolution/improvement of anti-PD1 mAb-related [*****]
 - a. No history of common toxicity criteria adverse events (CTCAE) Grade 4 irAEs from anti-PD1 mAb.
 - b. No history of CTCAE Grade 3 requiring steroid treatment. [*****]
 - c. Minimum of 4 weeks (washout period) from the last dose of anti-PD1 mAb.
4. Prior treatment with an approved BRAF inhibitor if BRAF V600 mutation-positive.
5. Age \geq 18 years of age on day of signing informed consent.
6. Has a performance status of 0 or 1 on the ECOG Performance Scale.
7. Have measurable disease based on RECIST v1.1, with at least one anatomically distinct lesion. Lesion or lesions must meet all the following baseline criteria:
 - a. Accessible for electroporation,
 - b. Must be accurately measured in at least one dimension (longest diameter in the plane of measurement is to be recorded) with a minimum size per RECIST v1.1.
- [*****]
8. Demonstrate adequate organ function as defined below. All screening laboratories should be performed within 10 days of treatment initiation.

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System	Laboratory Value
Hematological	
Absolute neutrophil count (ANC)	$\geq 1.5 \times 10^9/L$
Platelets	$\geq 100 \times 10^9/L$
Hemoglobin	$\geq 9 \text{ g/dL}$ or $\geq 5.6 \text{ mmol/L}$
Renal	
Creatinine* OR	$\leq 1.5 \times$ the upper limit of normal (ULN) OR
Measured or calculated creatinine clearance (CrCl)	$\geq 60 \text{ mL/min}$ for patient with creatinine levels $>1.5 \times$ institutional ULN
Glomerular filtration rate (GFR) can also be used instead of creatinine or CrCl	
Hepatic	
Total bilirubin	$\leq 1.5 \times$ ULN OR direct bilirubin \leq ULN for patients with total bilirubin levels $> 1.5 \times$ ULN
Aspartate aminotransferase (AST) and alanine aminotransferase (ALT)	$\leq 2.5 \times$ ULN OR $\leq 5 \times$ ULN for patients with liver metastases
Coagulation	
International Normalized Ratio (INR) or Prothrombin Time (PT)	$\leq 1.5 \times$ ULN unless patient is receiving anticoagulant therapy as long as PT or PTT is within therapeutic range of intended use of anticoagulants
Activated Partial Thromboplastin Time (aPTT)	
* Creatinine clearance should be calculated per institutional standard.	

9. Women of childbearing potential must have negative serum or urine pregnancy test within 72 hours prior to receiving the first study drug administration. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.

For women of childbearing potential, must be willing to use an adequate method of contraception from 30 days prior to the first study drug administration and 120 days following last day study drug administration[*****]

10. Male patients of childbearing potential must be surgically sterile, or must agree to use adequate method of contraception during the study and at least 120 days following the last day of study drug administration.
[*****]

11. Able and willing to provide written informed consent and to follow study instructions.

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Exclusion criteria

The patient must be excluded from participating in the trial if meet any of the following:

1. Patient has disease that is suitable for local therapy administered with curative intent.
2. Patient with a diagnosis of uveal melanoma.
3. Patient has a known additional malignancy that is progressing or requires active treatment. Exceptions include basal cell carcinoma of the skin, squamous cell carcinoma of the skin that has undergone potentially curative therapy or in situ cervical cancer.
4. Clinically active cerebral or any bone metastases. Patients with up to 3 (neurological performance status of 0) cerebral metastases may be enrolled, provided that all lesions have been adequately treated with stereotactic radiation therapy or gamma-knife therapy with no evidence of progression, and have not required steroids, for at least two months prior to enrolment.
5. Greater than 3 visceral metastases (this does not include nodal metastases associated with visceral organs). For patients with less than or equal to 3 visceral metastases, no lesion > 3 cm and liver lesions must meet RECIST v1.1 criteria for SD for at least 1 month prior to enrolment.
6. Patients with electronic pacemakers or defibrillators.
7. Patients who have a known history of Human Immunodeficiency Virus (HIV) (HIV 1/2 antibodies).
8. Patients who have known active Hepatitis B (e.g., HBsAg reactive) or Hepatitis C (e.g., HCV RNA [*****] is detected); Note: Patients who have been vaccinated against Hepatitis B and who are positive only for the Hepatitis B surface antibody are permitted to participate in the study.
9. Patient has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study drug. The use of physiologic doses of corticosteroids may be approved after consultation with the Sponsor.
10. Patients who have received a live-virus vaccination within 30 days of the first dose of treatment. Seasonal flu vaccines that do not contain live virus are permitted.
11. Patient has severe hypersensitivity (\geq Grade 3) to pembrolizumab and/or any of its excipients.
12. Patients who have received transfusion of blood products (including platelets or red blood cells) or administration of colony stimulating factors (including G-CSF, GM-CSF or recombinant erythropoietin) within 4 weeks prior to study Cycle 1, Day 1 (baseline).
13. Patient has a history of (non-infectious) pneumonitis that required steroids or current pneumonitis.
14. Patient has a history of interstitial lung disease.
15. Patient has an active infection requiring systemic therapy.

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16. Patient has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the trial, interfere with the patient's participation for the full duration of the trial, or is not in the best interest of the patient to participate, in the opinion of the treating investigator.
17. Patient has not recovered (i.e., \leq Grade 1 or at baseline) from adverse events due to a previously administered agent.
[****]
18. Participation in another clinical trial within 30 days of screening.
[****]
19. Patients who have had any chemotherapy, targeted small molecule therapy, radiation therapy or any immunotherapeutic after their confirmed progression on anti-PD-1 therapy.
20. Patient has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial.
21. Patients who are pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 120 days after the last dose of trial treatment.

Efficacy Endpoints

Primary Efficacy Endpoint:

- BORR by [****] RECIST v1.1 over 24 weeks

Secondary Efficacy Endpoints:

- ORR [****];
- DOR [****];
- PFS [****];
- [****]
OS.

Exploratory Endpoint:

Immune monitoring [****¹]

Safety Assessments and Outcomes

Safety assessments in the Core study and Extension phase will include:

- AEs
- Pembrolizumab AE of event(s) of clinical interest (ECI)
- Safety Laboratory
- ECOG performance status
- Physical examination
- Vital signs
- Assessment of durable procedural pain
- Concomitant medication

Primary safety outcomes:

1. Frequency, duration and severity of AEs and serious AEs (SAEs);
2. Incidence and shifts of clinically significant laboratory abnormalities; safety laboratory evaluations includes complete blood count (CBC), blood biochemistry and urinalysis

Safety outcome will be analyzed at end of Core study (24 weeks) and at the end of the study (EOS visit).

AEs and abnormal laboratories will be classified according to the National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE), version 4.03. If a laboratory finding is abnormal but not clinically significant (NCS) at baseline, post-baseline laboratory abnormalities will be reported as an AE only if there is worsening compared to baseline.

Progression of the cancer under study is not considered an adverse event unless it is drug-related by the investigator.

[****]

[****]

¹ [****]

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Appendix B

SUPPLY OF COMPOUND

Schedule of Deliveries for IT-pIL 12-EP

<u>Delivery Date</u>	<u>Quantity of Vials</u>
[****]	[****]
[****]	[****]
[****]	[****]
	[****]

Schedule of Deliveries for KEYTRUDA[®]

<u>Delivery Date</u>	<u>Quantity of Vials</u> <u>(Liquid – [****] vial)</u>
[****]	[****]
[****]	[****]
	[****]

COMPANY PRESS RELEASE

OncoSec Announces Clinical Collaboration with Merck to Evaluate Combination of ImmunoPulse® IL-12 and KEYTRUDA® (pembrolizumab) for Metastatic Melanoma

San Diego, CA – April XX, 2017 — OncoSec Medical Incorporated (“OncoSec”) (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, has entered a clinical trial collaboration and supply agreement with Merck (known as MSD outside the United States and Canada) to evaluate the combination of OncoSec’s ImmuoPulse® IL-12 with Merck’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a Phase II clinical trial, referred to as **PISCES**. The planned clinical trial will evaluate the safety and efficacy of the combination in patients with metastatic melanoma following disease progression on previous treatment with an anti-PD-1 therapy.

“We are honored to collaborate with Merck – one of the world’s leading cancer immuno-oncology companies – to help bring innovative cancer treatments to patients with unmet medical needs,” said Punit Dhillon, CEO and President of OncoSec. “This collaboration is supported by our recent clinical data demonstrating the potential ability of ImmuoPulse® IL-12 to rescue patients who do not initially respond to anti-PD-1 therapy in melanoma. In addition to our recent Fast Track Designation for this population, OncoSec is uniquely positioned to meaningfully impact clinical outcomes for patients who do not currently have any other options. By working with innovative immuno-oncology leaders, this alliance underpins OncoSec’s strategy to combine our ImmuoPulse® IL-12 program with checkpoint inhibitor therapies to advance the care of patients.”

Eligible patients for this Phase II study will be those with Stage III/IV metastatic melanoma who are progressing, or have progressed, on previous treatment with an anti-PD-1 therapy. . The collaboration agreement is between OncoSec Medical Incorporated and Merck, through a subsidiary. Under the agreement, OncoSec will sponsor and fund the study and Merck will provide KEYTRUDA. Additional details of the collaboration were not disclosed.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated, San Diego, CA, USA.

About PISCES

PISCES (Anti-PD-1 IL-12 Stage III/IV Combination Electroporation Study) will be a Phase II multicenter study of ImmuoPulse® IL-12 in combination with KEYTRUDA® in patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as Stage III or Stage IV. Eligible patients will be those with Stage III/IV metastatic melanoma who are progressing or have progressed on an approved anti-PD-1 therapy. The primary endpoint for this registration-directed trial will be best overall response rate (BORR).

About OncoSec Medical Incorporated

OncoSec is a biotechnology company developing DNA-based intratumoral immunotherapies with an investigational technology, ImmuoPulse®, for the treatment of cancer. ImmuoPulse® is designed to enhance the local delivery and uptake of DNA-based immune-targeting agents, such as IL-12. In Phase I and II clinical trials, ImmuoPulse® IL-12 has demonstrated a favorable safety profile and evidence of anti-tumor activity in the treatment of various solid tumors as well as a systemic clinical and immune response. OncoSec’s lead program, ImmuoPulse® IL-12, is currently in clinical development for metastatic melanoma and triple-negative breast cancer. The program’s current focus is on the significant unmet medical need in patients with melanoma who are refractory or non-responsive to anti-PD-1/PD-L1 therapies. In addition to ImmuoPulse® IL-12, the Company is also identifying and developing new immune-targeting agents for use with the ImmuoPulse® platform. For more information, please visit www.oncosec.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as “can,” “may,” “will,” “suggest,” “look forward to,” “potential,” “understand,” and similar references to future periods.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on management’s current preliminary expectations and are subject to risks and uncertainties, which may cause our results to differ materially and adversely from the statements contained herein. Potential risks and uncertainties that could cause actual results to differ from those predicted include, among others, the following: uncertainties inherent in pre-clinical studies and clinical trials, such as the ability to enroll patients in clinical trials and the risk of adverse events; unexpected new data, safety and technical issues; our ability to raise additional funding necessary to fund continued operations; and the other factors discussed in OncoSec’s filings with the Securities and Exchange Commission.

Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. OncoSec disclaims any obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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SUBSIDIARIES OF ONCOSEC MEDICAL INCORPORATED

Name of Subsidiary	State or Other Jurisdiction of Incorporation or Organization
OncoSec Medical Australia Pty, Ltd.	Australia

CERTIFICATIONS

I, Daniel J. O'Connor, certify that:

1. I have reviewed this Amendment No. 1 to Annual Report on Form 10-K of OncoSec Medical Incorporated; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

November 28, 2017

/s/ Daniel J. O'Connor

Daniel J. O'Connor

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATIONS

I, Richard Slansky, certify that:

1. I have reviewed this Amendment No. 1 to Annual Report on Form 10-K of OncoSec Medical Incorporated; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

November 28, 2017

/s/ Richard B. Slansky

Richard B. Slansky

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)
