

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

**FORM 20-F/A
(Amendment No. 1)**

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report _____

Commission file number: 001-38556

ENTERA BIO LTD.

(Exact name of Registrant as specified in its charter)

State of Israel

(Jurisdiction of incorporation or organization)

**Kiryat Hadassah
Minrav Building - Fifth Floor
Jerusalem, Israel
Tel: +972-2-532-7151**

(Address of principal executive offices)

**Dr. Phillip Schwartz, Chief Executive Officer
Kiryat Hadassah
Minrav Building - Fifth Floor
Jerusalem, Israel
Tel: +972-2-532-7151**

(Name, Telephone E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Name of each exchange on which registered
Ordinary Shares, par value of NIS 0.0000769	NASDAQ Capital Market
Warrants, each warrant exercisable for 0.5 shares of Ordinary Shares at an exercise price of \$8.4 per Ordinary Share.	NASDAQ Capital Market

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

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

11,459,780 Ordinary Shares, par value NIS 0.0000769 per share.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company (as defined in Rule 12b-2 of the Act).

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer
Emerging growth company

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Explanatory Note

This Amendment No. 1 (this “Amendment”) to our annual report on Form 20-F for the fiscal year ended December 31, 2018 (the “Form 20-F”) filed on March 28, 2019 (the “Original Filing Date”), is being filed solely to replace Exhibit 4.28 with the attached Exhibit 4.28 to reflect amendments to paragraph 4(a) of the Instructions as to Exhibits of Form 20-F, governing redaction of confidential information in material contracts, which became effective as of April 2, 2019.

In addition, the Company is including in this Amendment currently dated certifications from its Chief Executive Officer and Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002 as Exhibits 12.1 and 12.2, respectively. Because no financial statements have been included in this Form 20-F/A, paragraph 3 of the certifications have been omitted.

Except for the revised Exhibit, this Amendment does not amend any other information set forth in the Form 20-F. This Amendment speaks as of the Original Filing Date, does not reflect any events that may have occurred subsequent to the Original Filing Date, and does not modify or update in any way any disclosures made in the Form 20-F.

ITEM 19. EXHIBITS

EXHIBIT INDEX

**EXHIBIT
NUMBER**

DESCRIPTION OF DOCUMENT

4.28 *† [Research Collaboration and License Agreement, dated as of December 10, 2018, between Amgen Inc. and Entera Bio Ltd.](#)
12.1* [Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002](#)
12.2* [Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002](#)

* Filed herewith.

† Portions of this exhibit have been omitted because they are both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURES

Entera Bio Ltd. hereby certifies that it meets all of the requirements for filing on Form 20-F and this Amendment No. 1 thereto, and that it has duly caused and authorized the undersigned to sign this Amendment No. 1 to the annual report on its behalf.

ENTERA BIO LTD.

By: /s/ Phillip Schwartz
Dr. Phillip Schwartz
Title: Chief Executive Officer
Date: April 17, 2019

THE SYMBOL “[*]” INDICATES MATERIAL WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

RESEARCH COLLABORATION

AND

LICENSE AGREEMENT

by and between

AMGEN INC.

and

ENTERABIO LTD.

Dated as of December 10, 2018

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RESEARCH COLLABORATION AND LICENSE AGREEMENT

This Research Collaboration and License Agreement (“**Agreement**”) is entered into as of December 10, 2018 (the “**Effective Date**”) by and between Amgen Inc., a Delaware corporation having an address at One Amgen Center Drive, Thousand Oaks, California 91320, USA (“**Amgen**”) and EnteraBio Ltd., an Israeli company having an address at Minrav Building, 5th Floor, PO Box 12117, Jerusalem 91220, Israel (“**EnteraBio**”). Amgen and EnteraBio are each hereafter referred to individually as a “**Party**” and together as the “**Parties**”.

WHEREAS, Amgen has research, development, manufacturing and commercialization expertise for the development and commercialization of pharmaceutical and biologics products;

WHEREAS, EnteraBio has technology and expertise relating to oral drug delivery of large molecule products;

WHEREAS, Amgen and EnteraBio desire to collaborate in the performance of a preclinical research and development program for purposes of the discovery of clinical candidates from the Collaboration Programs (as defined below); and

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1. DEFINITIONS

All references to particular Exhibits, Articles or Sections mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits and Appendices hereto, the following words and phrases have the following meanings:

Section 1.1 “Abandoned Patent Right” has the meaning set forth in Section 8.2.3.

Section 1.2 “Affiliate” means, with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person, for as long as such control exists. For purposes of this Section, “control” means the direct or indirect ownership of more than fifty percent (50%) (or, if local law restricts foreign ownership, of the maximum ownership percentage that may, under such local law, be owned by foreign interests) of the voting or economic interest of a Person, or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

Section 1.3 “Agreement” has the meaning set forth in the Preamble.

Section 1.4 “Amgen” has the meaning set forth in the Preamble.

Section 1.5 “Amgen Acquiree” has the meaning set forth in Section 14.9.

Section 1.6 “Amgen Acquisition” has the meaning set forth in Section 14.9.

Section 1.7 “Amgen Indemnified Parties” has the meaning set forth in Section 10.1.1.

Section 1.8 “Amgen IP” means [*].

Section 1.9 “Amgen Licensed Know-How” means [*].

Section 1.10 “Amgen Patents” means [*].

Section 1.11 “Anti-Bribery and Anti-Corruption Laws” has the meaning set forth in Section 9.4(c)(i)(b).

Section 1.12 “Anti-Corruption Policies” has the meaning set forth in Section 9.4(c)(i)(a).

Section 1.13 “Background IP” means Patent Rights and Know-How (a) Controlled by a Party prior to the Effective Date or (b) Controlled by such Party during the Term, but not generated in the performance of the activities contemplated under this Agreement.

Section 1.14 “Blocking Patents” means as to a Product, in the case of Amgen, any Patent Rights Controlled by a Third Party that claim, in a particular country, the composition of matter or method of use of such Product, and which such Patent Rights would be infringed by the manufacture, use, offer for sale, sale, import, or export of such Product in such country.

Section 1.15 “Change of Control” means (a) the closing of the sale, transfer, exclusive license or other disposition of all or substantially all of EnteraBio’s assets or intellectual property, (b) the consummation of the merger or consolidation of EnteraBio with or into another entity (except a merger or consolidation in which the holders of capital stock of EnteraBio immediately prior to such merger or consolidation continue to hold more than 50% of the voting power of the capital stock of EnteraBio or the surviving or acquiring entity), (c) the closing of the transfer (whether by merger, consolidation or otherwise), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter of EnteraBio’s securities), of EnteraBio’s securities if, after such closing, such person or group of affiliated persons would hold 50% or more of the outstanding voting stock of EnteraBio (or the surviving or acquiring entity) or (d) a liquidation, dissolution or winding up of EnteraBio.

Section 1.16 “Collaboration IP” means [*].

Section 1.17 “Collaboration Know-How” means [*].

Section 1.18 “Collaboration Patents” means [*].

Section 1.19 “Collaboration Program(s)” [*].

Section 1.20 “Combination Product” has the meaning set forth in Section 1.67.

Section 1.21 “Commercially Reasonable Efforts” means, with respect to a Party, [*].

Section 1.22 “Confidential Disclosure Agreement” means that certain Confidential Disclosure Agreement entered into between the Parties as of May 5, 2017, as amended.

Section 1.23 “Confidential Information” has the meaning set forth in Section 12.1.1.

Section 1.24 “Control” or **“Controlled”** means, with respect to any Know-How, Patent Right, or other intellectual property right, the possession (whether by ownership or license) by a Party or its Affiliate of the ability to grant to the other Party a license or access as provided herein to such Know-How, Patent Right, or other intellectual property right, without violating the terms of any agreement or other arrangement with any Third Party, or being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access; [*].

Section 1.25 “Cover” means, with respect to an issued and unexpired claim of a Patent Right and a product, such claim would (absent a license thereunder or ownership thereof) be Infringed by the Exploitation of such product, and with respect to a Patent Right which is a pending application of a patent, the application shall be treated as if issued in the form then currently being prosecuted. Cognates of the word **“Cover”** have correlative meanings.

Section 1.26 “Defending Party” has the meaning set forth in Section 8.4.

Section 1.27 “Derivatives” has the meaning set forth in Section 8.1.3.

Section 1.28 “Disclosing Party” has the meaning set forth in Section 12.1.1.

Section 1.29 “EMA” means the European Medicines Agency or any successor entity thereto.

Section 1.30 “Enforcing Party” has the meaning set forth in Section 8.5.3.

Section 1.31 “EnteraBio” has the meaning set forth in the Preamble.

Section 1.32 “EnteraBio Acquiree” has the meaning set forth in Section 14.10.

Section 1.33 “EnteraBio Acquisition” has the meaning set forth in Section 14.10.

Section 1.34 “EnteraBio IP” means [*].

Section 1.35 “EnteraBio Indemnified Parties” has the meaning set forth in Section 10.1.2.

Section 1.36 “EnteraBio Licensed Know-How” means [*].

Section 1.37 “EnteraBio Patents” means [*].

Section 1.38 “EnteraBio Platform” means the technology platform as agreed upon in writing by the Parties.

Section 1.39 “E.U.” means those countries, nations, states or other territories under the jurisdiction of the EMA, as such jurisdiction may change from time to time.

Section 1.40 “Executive Officers” means (a) with respect to EnteraBio, the Chief Executive Officer, and (b) with respect to Amgen, a Vice President, or in the case of both parties, any other person that such officer designates, who has the authority to make decisions on behalf of such respective company, from time to time.

Section 1.41 “Exploit” means to discover, research, develop, make, have made, use, offer for sale, sell, have sold, import, export, or otherwise exploit, or transfer possession of or title in. Cognates of the word “**Exploit**” shall have correlative meanings.

Section 1.42 “FDA” means the United States Food and Drug Administration or any successor entity thereto.

Section 1.43 “First Commercial Sale” means, [*].

Section 1.44 “First Year” has the meaning set forth in Section 7.1.2(a).

Section 1.45 “First Year FTE Payment” has the meaning set forth in Section 7.1.2(a).

Section 1.46 “GAAP” means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.

Section 1.47 “Generic Version” means, with respect to a Product, any pharmaceutical product that (a) is sold by a Third Party that is not a licensee or sublicensee of Amgen or its Affiliates, or any of their licensees or sublicensees; (b) contains the same active pharmaceutical ingredient as such Product; and (c) is approved in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Product as determined by the applicable Regulatory Authority, including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FD&C Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), (ii) in the E.U. pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (iii) in any other country or jurisdiction pursuant to any equivalent of such provisions.

Section 1.48 “GLP Toxicology Study” means a toxicology study that meet the requirements set forth in 21 CFR Part 58 pertaining to good laboratory practice for use or intended for use in an IND and are required to be included in the filing of an IND, but excluding any toxicology study performed in the course of evaluating compounds prior to selection of a development candidate by the JRC.

Section 1.49 “GMP” or “Good Manufacturing Practices” means the then-current Good Manufacturing Practices required by the FDA, as set forth in the U.S. Food, Drug and Cosmetic Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

Section 1.50 “Governmental Authority” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

Section 1.51 “Improvement” means an advancement, modification, development or improvement.

Section 1.52 “IND” means, with respect to the United States, an investigational new drug application as defined in applicable regulations promulgated by the FDA and filed with the FDA for human clinical testing of a drug or, with respect to any jurisdiction other than the United States, an equivalent filing thereof.

Section 1.53 “Indemnitee” has the meaning set forth in Section 10.1.3.

Section 1.54 “Indemnitor” has the meaning set forth in Section 10.1.3.

Section 1.55 “Initial Program” means the initial Collaboration Program as agreed upon in writing by the Parties.

Section 1.56 “Initiation” means, [*]. Cognates of the word “**Initiation**” have correlative meanings.

Section 1.57 “Issuing Party” has the meaning set forth in Section 12.2.2.

Section 1.58 “Joint Research Committee” or “JRC” has the meaning set forth in Section 2.1.1.

Section 1.59 “Know-How” means proprietary techniques, technology, trade secrets, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, compositions of matter, cells, cell lines, assays, animal models, reagents and other physical, biological, or chemical material.

Section 1.60 “Law” means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

Section 1.61 “Licensed Field” means [*].

Section 1.62 “Losses” has the meaning set forth in Section 10.1.1.

Section 1.63 “Marketing Approval” means all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country, necessary for the manufacture, use, storage, import, marketing and sale (including with respect to pricing and reimbursement) of a Product in such country.

Section 1.64 “Material Anti-Corruption Law Violation” means a violation of any Anti-Bribery and Anti-Corruption Laws relating to the subject matter of this Agreement which would, if it were publicly known, in the reasonable view of a Party, have a material adverse effect on it or its reputation because of its relationship with the other Party.

Section 1.65 “Milestone Events” has the meaning set forth in Section 7.2.1.

Section 1.66 “Milestone Payments” has the meaning set forth in Section 7.2.1.

Section 1.67 “Net Sales” means, with respect to a certain time period and Product, [*]

[*]

[*]

[*]

[*]

[*]

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[*].

Section 1.68 “Non-Publishing Party” has the meaning set forth in Section 12.3.

Section 1.69 “Party” and **“Parties”** has the meaning set forth in the Preamble.

Section 1.70 “Patent Rights” means (a) all patents, priority patent filings and patent applications, and (b) any renewal, divisional, continuation (in whole or in part), or request for continued examination of any of such patents, and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reviews, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

Section 1.71 “Person” means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

Section 1.72 “Phase 1 Clinical Trial” means any first in human clinical trial of a Product conducted mainly to evaluate the safety of chemical or biologic agents or other types of inventions (e.g., a new radiation therapy technique) that would satisfy the requirements of 21 CFR § 312.21(a) or its non-U.S. equivalents.

Section 1.73 “Phase 2 Clinical Trial” means any human clinical trial of a Product conducted mainly to test the effectiveness of chemical or biologic agents or other types of interventions for purposes of identifying the appropriate dose for a Phase 3 Clinical Trial for a particular indication or indications that would satisfy the requirements of 21 CFR § 312.21(b) or its non-United States equivalents. A “**Phase 2/3 Clinical Trial**” shall be deemed to be a Phase 2 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

Section 1.74 “Phase 3 Clinical Trial” means any human clinical trial of a Product designed to: (a) establish that such Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) support regulatory approval of such Product, that would satisfy the requirements of 21 CFR § 312.21(c) or its non-U.S. equivalents. A “**Phase 2/3 Clinical Trial**” shall be deemed to be a Phase 3 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 3 component, in accordance with the applicable protocol.

Section 1.75 “Preclinical Research & Development” means, with respect to a particular Collaboration Program, any discovery, research, design, preclinical and process development activities relating to such Collaboration Program, as set forth in the applicable Work Plan.

Section 1.76 “Preclinical R&D Term” means, [*].

Section 1.77 “Product” means a pharmaceutical or biologic product [*].

Section 1.78 “Public Official or Entity” means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

Section 1.79 “Publishing Party” has the meaning set forth in Section 12.3.

Section 1.80 “Receiving Party” has the meaning set forth in Section 12.1.1.

Section 1.81 Regulatory Authority” means any Governmental Authority or other authority responsible for granting Marketing Approvals for Products, including the FDA, EMA and any corresponding national or regional regulatory authorities.

Section 1.82 “Regulatory Filing” means any filing with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Product.

Section 1.83 “Release” has the meaning set forth in Section 12.2.2.

Section 1.84 “Reviewing Party” has the meaning set forth in Section 12.2.2.

Section 1.85 “Royalty Term” has the meaning set forth in Section 7.5.2.

Section 1.86 “Sale Transaction” has the meaning set forth in Section 14.8.

Section 1.87 “Second Year” has the meaning set forth in Section 7.1.2(b).

Section 1.88 “Second Year FTE Payment” has the meaning set forth in Section 7.1.2(b).

Section 1.89 “Second Year Prepayment Amount” has the meaning set forth in Section 7.1.2(f).

Section 1.90 “Selling Party” has the meaning set forth in Section 1.90.

Section 1.91 “Sublicensee(s)” means shall mean any Third Party to which a Party has granted a sublicense under this Agreement.

Section 1.92 “Termination Party” means (a) Amgen, in the case of termination by (i) Amgen pursuant to Sections 13.3.1, 13.3.2 or (ii) EnteraBio pursuant to Section 13.2.1, and (b) EnteraBio, in the case of termination by Amgen pursuant to Section 13.3.1.

Section 1.93 “Term” has the meaning set forth in Section 13.1.

Section 1.94 “Territory” means the entire world.

Section 1.95 “Third Party” means a Person other than (a) Amgen or any of its Affiliates and (b) EnteraBio or any of its Affiliates.

Section 1.96 “Third Party Acquirer” has the meaning set forth in Section 14.9.

Section 1.97 “Third Party Claim” has the meaning set forth in Section 10.1.1.

Section 1.98 “U.S.” means the United States of America and its territories and possessions.

Section 1.99 “Valid Claim” means a claim in an issued and unexpired Patent Right that has not been disclaimed, revoked, held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through re-examination, re-issue, disclaimer or otherwise, or lost in an interference proceeding; [*].

Section 1.100 “VAT” has the meaning set forth in Section 7.11.2.

Section 1.101 “Work Plan” means, for each Collaboration Program, the comprehensive plan, setting forth the research strategy, activities and deliverables for the Preclinical Research & Development of Products under the applicable Collaboration Program, which shall be agreed upon in writing by the Parties.

ARTICLE 2. RESEARCH COLLABORATION

Section 2.1 Management.

2.1.1 Overview. Within thirty (30) days after the Effective Date, the Parties shall establish a joint research committee (the “**Joint Research Committee**” or the “**JRC**”) which shall manage the progress and direction of Preclinical Research & Development collaboration between the Parties.

2.1.2 Joint Research Committee.

(a) **Composition.** The Joint Research Committee shall be comprised of three (3) named representatives of each Party (or such other number as the Parties may agree). The JRC will be led by two (2) co-chairs, one (1) appointed by each Party. Within thirty (30) days after the Effective Date, each Party shall designate by written notice to the other Party its initial representatives on the JRC. Each Party may replace one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change.

(b) **Function and Powers of the JRC.** The JRC shall, consistent with the terms and conditions set forth in this Agreement:

- (i) amend a Work Plan, provided that the JRC shall have no authority, without the express written consent of both Parties, to amend a Work Plan in a manner that would require a Party to incur aggregate expenses that are higher than those contemplated by the previously agreed upon Work Plan;
- (ii) review progress of the Preclinical Research & Development against the goals and/or deliverables set forth in a Work Plan;
- (iii) extend the Preclinical R&D Term for one or more Collaboration Programs;
- (iv) identify Product development candidates, subject to the procedure in Section 3.6 for selecting Post-Effective Date Programs, provided however that Amgen shall have the right to elect, in its sole discretion, whether to Initiate a GLP Toxicology Study of a Product pursuant to Section 4.5.1; establish subcommittees, as appropriate, as described more fully in Section 2.1.2(d) below;
- (v) direct and oversee any subcommittee;
- (vi) approve annual Out-of-Pocket Expense budget, in accordance with Section 3.1;
- (vii) resolve disputed matters that may arise at any subcommittee; and

- (viii) perform any and all tasks and responsibilities that are expressly attributed to the JRC under this Agreement.

Subject to Section 14.12, the JRC shall have the foregoing authority on a Collaboration Program-by-Collaboration Program basis only during the applicable Preclinical R&D Term. The JRC shall only have such powers as are specifically assigned to it in this Agreement, and such powers shall be subject to the terms and conditions set forth in this Agreement. Without limiting the generality of the foregoing, the JRC shall have no power to amend or modify this Agreement or to amend, modify or waive compliance with the terms of this Agreement, and no decision of the JRC shall be in contravention of any terms and conditions of this Agreement.

(c) **Meetings.** The Joint Research Committee shall meet at least twice per year or more or less often as otherwise agreed by the Parties, and such meetings may be conducted by telephone, videoconference or in person as determined by the co-chairs. As appropriate, and provided that not less than two (2) business days' prior written notice has been given to the other Party, other employees of the Parties may attend Joint Research Committee meetings as observers, but a Party shall not bring a Third Party to a meeting without the other Party's prior consent, which consent shall not be unreasonably withheld. Each Party may also call for special meetings of the Joint Research Committee with reasonable prior written notice to the other Party (it being agreed that at least ten (10) business days shall constitute reasonable notice) to resolve particular matters requested by such Party and within the decision-making responsibility of the Joint Research Committee. Minutes will be kept of all JRC meetings and will reflect material decisions made at such meetings. Meeting minutes will be prepared by the Parties on a rotating basis and sent to each member of the JRC for review and approval promptly following each meeting. Minutes will be deemed approved unless a member of the JRC objects to the accuracy of such minutes within thirty (30) days of receipt. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.

(d) **Subcommittees.** The JRC may establish and disband subcommittees as deemed necessary by the JRC. Each such subcommittee shall consist of the same number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its representatives on written notice to the other Party or to send a substitute representative to any subcommittee meeting. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in Article 12. Except as expressly provided in this Agreement, no subcommittee shall have the authority to bind the Parties hereunder and each subcommittee shall report to the JRC. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.

2.1.3 Cooperation. Each Party shall provide the JRC such information as reasonably required under any Work Plan, or as reasonably requested by the other Party and reasonably available, relating to the progress of the goals or performance of activities under such Work Plan.

2.1.4 Decisions. Other than as expressly set forth herein, in order to make any decision required of it hereunder, the JRC must have present (in person, by videoconference or telephonically) at least the co-chair of each Party (or his/her designee for such meeting). Decisions of the JRC shall be by consensus, with each Party having one (1) vote. If the JRC cannot reach consensus or a dispute arises, in each case, that cannot be resolved in good faith discussions of the JRC for a period of at least sixty (60) days (whether the matter originated at the JRC or within a subcommittee), the co-chair of either Party may

cause such dispute to be referred to the Executive Officers for resolution, [*].

2.1.5 Discontinuation of JRC. Subject to Section 14.12, the JRC shall continue to exist and execute its functions and powers set forth herein until the expiration of the last Preclinical R&D Term.

ARTICLE 3. PRECLINICAL RESEARCH & DEVELOPMENT ACTIVITIES; EXCLUSIVITY

Section 3.1 Preclinical Research & Development of Products.

3.1.1 Within thirty (30) days of the Effective Date, each Party shall commence Preclinical Research & Development activities assigned to it under the Work Plan for the Initial Collaboration Program. During the Preclinical R&D Term of any Collaboration Program, each Party shall use its Commercially Reasonable Efforts to conduct its Preclinical Research & Development activities of the Products in accordance with the applicable Work Plan. In performing its activities under each Work Plan, each Party shall (and shall cause its Affiliates and Third Party subcontractors, as applicable, to) perform such activities in compliance with all applicable scientific standards, laboratory practices and all applicable Laws, and engage and appropriately control adequately qualified personnel.

3.1.2 The Parties agree that Amgen shall prepay or reimburse EnteraBio for its costs (i.e., internal and out-of-pocket expenses, including costs of shipping Materials, as described in Section 3.5) with respect to the Preclinical Research & Development activities EnteraBio conducts (including through its Affiliates or Third Party contractors) under each Work Plan (collectively, “**Preclinical Research & Development Costs**”) as set forth in this Section 3.1.2, which, for clarity, subject to the first sentence of Section 3.1.2(a), shall be in addition to the payments to EnteraBio contemplated in Sections 3.7 (Extension of Preclinical R&D Term), 7.1.1 (Technology Access Payment; Upfront Payment), 7.2 (Milestone Payments) and 7.3 (Royalties).

(a) *Internal Preclinical Research & Development Costs.* The Parties agree that, unless otherwise agreed in writing, the Amgen payments to EnteraBio contemplated in Section 7.1.1 (Technology Access Payment; Upfront Payment) and 7.1.2 (R&D Costs) shall cover EnteraBio’s internal Preclinical Research and Development Costs for the first two years of each Collaboration Program. [*].

(b) *Out-of-Pocket Preclinical Research & Development Costs.* On an annual basis, the JSC shall discuss in good faith and approve an annual budget for EnteraBio out-of-pocket Preclinical Research and Development Costs for each Collaboration Program (each, an “**Annual Out-of-Pocket Budget**”), which shall include an agreed-upon timeline for any Amgen prepayment of anticipated out-of-pocket Preclinical Research & Development Costs. Unless otherwise agreed to by the Parties in writing, following approval of the EnteraBio Out-of-Pocket Budget, Amgen shall prepay and/or reimburse, as applicable, EnteraBio’s reasonably documented out-of-pocket Preclinical Research & Development Costs in accordance with the Annual Out-of-Pocket Budget. In the event that Amgen prepays an amount of out-of-pocket Preclinical Research and Development Costs and such amount of such costs were not incurred by EnteraBio during such year, then, at Amgen’s option, EnteraBio shall either promptly refund to Amgen the remaining prepayment amount or apply such amount against the following year’s out-of-pocket Preclinical Research and Development Costs.

(c) *No Obligation to Incur Preclinical Research & Development Costs.* Notwithstanding anything in this Agreement to the contrary, EnteraBio shall have no obligation to conduct (or engage any Affiliate or Third Party subcontractor to conduct) any Preclinical Research & Development activity if the Parties have not agreed on Amgen’s reimbursement of the EnteraBio internal and out-of-pocket Preclinical Research & Development Costs incurred in connection with such activity pursuant to Section 3.1.2(a) and/or (b).

Section 3.2 Subcontracting. Each Party may engage its Affiliates, or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform certain of its obligations under this Agreement; [*]. Any Third Party subcontractor to be engaged by a Party to perform such Party’s obligations set forth in this Agreement will meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity. The activities of any such Third Party subcontractors will be considered activities of such subcontracting Party under this Agreement. The subcontracting Party will be responsible for ensuring compliance by any such Third Party subcontractors with the terms of this Agreement, as if such Third Party(ies) are such Party hereunder. Each subcontracting Party will, and will contractually require that its Affiliates and subcontractors, if any, conduct the relevant Preclinical Research & Development activities in accordance with such subcontracting Party’s commitments with respect to the applicable Work Plan.

Section 3.3 Data. EnteraBio shall, at Amgen’s written request, promptly make available to Amgen all data generated by or on behalf of EnteraBio and/or its Affiliates that is related to any and all Collaboration Programs and/or Products during the applicable Preclinical R&D Term. Amgen shall, at EnteraBio’s written request, promptly make available to EnteraBio all data generated by or on behalf of Amgen and/or its Affiliates that is reasonably necessary by EnteraBio to conduct its activities contemplated under the applicable Work Plan during the applicable Preclinical R&D Term and to carry out its obligations and exercise its rights under this Agreement.

Section 3.4 Exclusivity.

3.4.1 [*].

Section 3.5 Material Transfer. To facilitate the Preclinical Research & Development, either Party may provide to the other Party certain biological materials or chemical compounds, owned by or licensed to the supplying Party for use by the other Party in furtherance of Preclinical Research & Development (such materials or compounds provided hereunder are referred to, collectively, as “**Materials**”). Except as otherwise expressly provided under this Agreement, all such Materials delivered to the other Party shall remain the sole property of the supplying Party, shall be used only in furtherance of the exercise of rights or performance of obligations under this Agreement and in accordance with this Agreement and solely under the control of the other Party, shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects or in animals intended for food use, in each case unless otherwise specifically contemplated hereunder), and will be used in compliance with all applicable Law. The provision of Materials to the receiving Party hereunder does not grant such Party any rights other than those specifically granted in this Agreement. Delivery of the Materials shall be EXW Incoterms 2010 (the supplying Party’s facilities). The receiving Party shall bear all responsibility for the shipped Materials thereafter, provided however, that Amgen shall bear the entire costs of transferring the Materials to EnteraBio and the insurance costs, to the extent applicable. The receiving Party shall be responsible for any and all consents, approvals, authorizations or other permits necessary for the use, handling, transfer, and/or storage of the Materials. The receiving Party shall: (a) receive the Materials; (b) promptly notify the supplying Party when the Materials have been received; and (c) forward to the supplying Party any applicable chain of custody forms, in-transport temperature record(s) and receipt verification documentation and such other documentation reasonably requested by the supplying Party. The receiving Party shall be responsible for import clearance (including preparing any necessary documentation with respect thereto) and making entry of shipment. The supplying Party shall provide the relevant shipping documentation, pro forma invoice and airway bill, together with such other documentation necessary for the use, handling, transfer, and/or storage of the Materials. The Materials supplied under this Section 3.5 are supplied “as is” and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known. Except as expressly set forth herein, THE MATERIALS ARE WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY. During the Preclinical R&D Term for any Collaboration Program, for record-keeping purposes, the Parties shall compile a list (that shall include the type of material, quantity, shipping date and any other relevant details) on a quarterly basis setting forth the Materials provided to/from each Party, which document shall be signed by an authorized representative of each Party. For clarity, this Section 3.5 shall apply during the applicable Preclinical R&D Term only, after which the Parties will enter into an appropriate material transfer agreement with respect to any transfer of Materials, which agreement will be subject to this Agreement and will be interpreted consistent with the terms hereof.

Section 3.6 Post-Effective Date Programs. At any time within the [*] period following the Effective Date, Amgen shall have the right to select up to two (2) additional Collaboration Programs (each, a “**Post-Effective Date Program**”). During such aforementioned [*] period, Amgen may propose by written notice to EnteraBio any Post-Effective Date Program. Upon EnteraBio’s receipt of any proposed Post-Effective Date Program, the Parties shall discuss in good faith the proposed program and negotiate a reasonable Work Plan related thereto. [*]. In the event that Amgen proposes any Post-Effective Date Program(s) within the applicable [*] period and the Parties are ultimately unable to agree on any such Post-Effective Date Program or the Work Plan related thereto, Amgen shall be entitled to propose alternative Post-Effective Date Program(s) in place of the earlier proposed program(s) to which the Parties are unable to agree during such [*] period.

Section 3.7 Extension of Preclinical R&D Term. [*].

Section 3.8 [*].

ARTICLE 4. LICENSE GRANT

Section 4.1 License Grant.

4.1.1 Preclinical License. During the Preclinical R&D Term for each Collaboration Program, EnteraBio hereby grants to Amgen a non-exclusive, worldwide, royalty-free right under EnteraBio IP solely to conduct Preclinical Research & Development as contemplated to be performed by Amgen under each Work Plan. During the Preclinical R&D Term for each Collaboration Program, Amgen hereby grants to EnteraBio a non-exclusive, worldwide, royalty-free right under Amgen IP solely to conduct Preclinical Research & Development as contemplated to be performed by EnteraBio under each Work Plan.

4.1.2 License Grant to Amgen. Subject to the terms and conditions of this Agreement, EnteraBio hereby grants to Amgen an exclusive (even as to EnteraBio and its Affiliates, except as expressly set forth herein and subject to EnteraBio and its Affiliates retaining the non-exclusive rights reasonably necessary or useful to perform EnteraBio's obligations under each Work Plan), royalty-bearing, sublicenseable (but only in accordance with Section 4.2), license under EnteraBio IP to Exploit Products in the Licensed Field in the Territory during the Term.

Section 4.2 Sublicenses. Amgen and its Affiliates shall be entitled, without the prior consent of EnteraBio, to grant one or more sublicenses under the licenses granted to Amgen under Section 4.1, in full or in part, by means of written agreement to Third Parties (with the right to sublicense through multiple tiers); *provided, however*, that as a condition precedent to and requirement of any such sublicense: (a) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement; and (b) Amgen will continue to be responsible for full performance of Amgen's obligations under this Agreement and will be responsible for all actions of such Sublicensee as if such Sublicensee were Amgen hereunder.

Section 4.3 Transfer of Know-How. Amgen shall transfer to EnteraBio the Amgen Licensed Know-How contemplated to be so transferred as set forth in the applicable Work Plan. EnteraBio shall transfer to Amgen the EnteraBio Licensed Know-How contemplated to be so transferred as set forth in the applicable Work Plan.

Section 4.4 No Other Rights. No right or license under any Patent Rights or other intellectual property rights of a Party is granted or shall be granted by implication to the other Party, and each Party covenants not to practice or use any Patent Rights or other intellectual property rights of the other Party except pursuant to the licenses expressly granted in this Agreement or any other written agreement between the Parties. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement.

Section 4.5 Initiation of a GLP Toxicology Study.

4.5.1 [*].

4.5.2 [*]

ARTICLE 5. REGULATORY MATTERS

Section 5.1 Amgen Responsibilities. Except as expressly provided in the Work Plans, Amgen will be solely responsible for the preparation, submission and maintenance of all Regulatory Filings and obtaining all Marketing Approvals with respect to Products. EnteraBio will reasonably cooperate with Amgen, at Amgen's reasonable request and expense, with respect to any regulatory matters related to Products. Amgen will own all right, title and interest in and to any and all Regulatory Filings and Marketing Approvals and all such Regulatory Filings and Marketing Approvals will be held in the name of Amgen or its designee, and EnteraBio will execute all documents and take all actions as are reasonably requested by Amgen to vest such title in Amgen or such designee, as applicable.

Section 5.2 Regulatory Updates. Amgen shall keep EnteraBio reasonably informed of all material regulatory developments relating to Products in the Territory through the annual development reports under Section 6.3 or as otherwise reasonably requested by EnteraBio from time to time.

ARTICLE 6. DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION MATTERS

Section 6.1 General.

6.1.1 Products. Following the Effective Date and at all times during the Term, except as otherwise expressly set forth herein, Amgen shall be responsible for, and shall bear all costs associated with, the research, development, manufacture and commercialization of Products, including development, distribution, marketing and sales activities. For clarity, after completion of the applicable Work Plan, Amgen shall continue to have the right to conduct Preclinical Research & Development with respect to the applicable Products. Subject to the express written terms of this Agreement, all decisions concerning the discovery, research, development, marketing and sales of Products including the clinical and regulatory strategy, design, sale, price and promotion of Products covered under this Agreement shall be within the sole discretion of Amgen. Upon [*] EnteraBio will transfer (subject to the license grant in Section 4.1.2) to Amgen all EnteraBio Licensed Know-How, at Amgen's costs and expense, as is reasonably necessary for Amgen to manufacture, develop and seek Marketing Approval for the applicable Products, including all materials for supporting regulatory filings consistent with Amgen's obligations under Article 5. Amgen understands and acknowledges that EnteraBio Licensed Know-how constitutes highly sensitive and Confidential Information of EnteraBio and prior to any transfer to any Third Party, Amgen will notify EnteraBio to discuss the proposed transfer to ensure the reasonable safeguards are in place with regard to maintaining the confidentiality of EnteraBio Licensed Know-How.

Section 6.2 Diligence. Each Party shall use Commercially Reasonable Efforts to carry out its obligations under each Work Plan. Following [*] Amgen shall (directly and/or through one or more Affiliates and/or Sublicensees) use Commercially Reasonable Efforts to develop and commercialize the applicable Product under such Collaboration Program in the Territory.

Section 6.3 Reports. For each Product, during the period from the end of the applicable Preclinical R&D Term until the First Commercial Sale of such Product, Amgen shall provide EnteraBio with reports [*] per Calendar Year of the status of Amgen's and its Affiliates' and Sublicensees' activities related to the Exploitation of such Product during the preceding [*] period. In addition, the Parties shall conduct [*] teleconference meetings to discuss the progress of each Collaboration Program. All reports and other Information provided by Amgen under this Section 6.3 will be Amgen's Confidential Information subject to the terms of Article 12.

ARTICLE 7. FEES, ROYALTIES, & PAYMENTS

Section 7.1 Technology Access Payment; Upfront Payment and R&D Funding.

7.1.1 Technology Access Payment; Upfront Payment. For the Initial Program, Amgen shall pay to EnteraBio a non-refundable, non-creditable payment equal to Seven Hundred and Twenty Five Thousand Dollars (\$725,000) within thirty (30) days after the Effective Date (the "**Technology Access Payment**"). For each Post Effective-Date Program, Amgen shall pay to EnteraBio a non-refundable, non-creditable payment equal to [*] within thirty (30) days of the parties entering into the applicable Work Plan (the "**Upfront Payment**").

7.1.2 R&D Costs.

(a) Amgen shall pay to EnteraBio for the performance of EnteraBio's activities under the Work Plan of each Post Effective-Date Program during the one (1) year period following the date in which the Parties agree in writing on the initiation of the applicable Post Effective-Date Program (the "**First Year**"), an aggregate amount of Two Hundred and Twenty-Five Thousand Dollars (\$225,000) (such payment amount contemplated in this Section 7.1.2(a), the "**First Year R&D Payment**").

(b) Amgen shall pay to EnteraBio for the performance of EnteraBio's activities under the Work Plan of each Collaboration Program, during the one (1) year period following the one (1) year anniversary of the date in which the Parties agreed in writing on the initiation of the applicable Collaboration Program, which for the Initial Program shall mean the Effective Date (the "**Second Year**"), an aggregate amount of Four Hundred and Fifty Thousand Dollars (\$450,000) (such payment amount contemplated in this Section 7.1.2(b), the "**Second Year R&D Payment**").

(c) Within thirty (30) days after the initiation of the applicable Post Effective-Date Program, Amgen shall pay to EnteraBio an amount equal to Two Hundred Twenty-Five Thousand Dollars (\$225,000) as a prepayment for the First Year R&D Payment.

(d) Within thirty (30) days after the one (1) year anniversary of the Effective Date, or the initiation of the applicable Collaboration Program, as applicable, Amgen shall pay to EnteraBio an amount equal to Two Hundred Twenty-Five Thousand Dollars (\$225,000) as a prepayment for the Second Year R&D Payment.

(e) Within thirty (30) days after the two (2) year anniversary of the Effective Date, or the initiation of the applicable Collaboration Program, as applicable, Amgen shall pay to EnteraBio an amount equal to Two Hundred Twenty-Five Thousand Dollars (\$225,000) for the remaining balance of the Second Year R&D Payment.

(f) The Parties shall discuss in good faith additional Amgen payments to EnteraBio for R&D activities performed by EnteraBio under the Work Plan of any Collaboration Program following the Second Year.

Section 7.2 Milestone Payments.

7.2.1 Amgen shall pay to EnteraBio one-time milestone payments (“**Milestone Payments**”) following the first occurrence of the corresponding milestone events (“**Milestone Events**”) as set forth in the following tables:

(i) Milestone Payments for the Initial Program, subject to Section 3.8:

(a) GLP Toxicology Study Milestone Events for the Initial Program

<u>Milestone Event</u>	<u>Milestone Payment</u>
Initiation of first GLP Toxicology Study of a Product under the Initial Program	[*]

(b) Other Development Milestone Events for the Initial Program

<u>Milestone Event</u>	<u>Milestone Payment</u>
Initiation of first Phase 1 Clinical Trial of a Product under the Initial Program	[*]
Initiation of first Phase 2 Clinical Trial of a Product under the Initial Program	[*]
Initiation of first Phase 3 Clinical Trial of a Product under the Initial Program	[*]

(c) Commercial Milestone Events for the Initial Program

<u>Milestone Event</u>	<u>Milestone Payment</u>
First Commercial Sale of a Product under the Initial Program	[*]
Worldwide Net Sales of Products under the Initial Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the Initial Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the Initial Program exceed [*] in a calendar year	[*]

(ii) Milestone Payments for each of the Second and Third Collaboration Program:

(a) Development Milestone Events for each of the Second and Third Collaboration Program

<u>Milestone Event</u>	<u>Milestone Payment</u>
Initiation of first GLP Toxicology Study of a Product under the applicable Post-Effective Date Program	[*]

(b) Development Milestone Events for each of the Second and Third Collaboration Program

<u>Milestone Event</u>	<u>Milestone Payment</u>
Initiation of first Phase 1 Clinical Trial of a Product under the applicable Post-Effective Date Program	[*]

<u>Milestone Event</u>	<u>Milestone Payment</u>
Initiation of first Phase 2 Clinical Trial of a Product under the applicable Post-Effective Date Program	[*]
Initiation of first Phase 3 Clinical Trial of a Product under the applicable Post-Effective Date Program	[*]

(c) Commercial Milestone Events for each of the Second and Third Collaboration Program

<u>Milestone Event</u>	<u>Milestone Payment</u>
First Commercial Sale of a Product under the applicable Post-Effective Date Program	[*]
Worldwide Net Sales of Products under the applicable Post-Effective Date Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the applicable Post-Effective Date Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the applicable Post-Effective Date Program exceed [*] in a calendar year	[*]

7.2.2 The Parties agree that Amgen shall pay to EnteraBio the applicable Milestone Payment in the manner described below after the first occurrence of the applicable Milestone Event with respect to the first Product under a given Collaboration Program. For clarity, each Milestone Payment payable pursuant to Section 7.2.1(i) and (ii), as applicable, is payable only once per Collaboration Program and the maximum Milestone Payment amount payable for Products with respect to the Initial Program under Section 7.2.1(i) and [*]. The maximum Milestone Payment amount payable for Products with respect to each Post-Effective Date Program is [*]. No Milestone Payment shall be payable for subsequent or repeated achievements of such Milestone Event with one or more of the same or different Products under a Collaboration Program. Each of the Milestone Payments shall be non-refundable and non-creditable. Amgen shall report to EnteraBio its achievement of each Milestone Event for which payment to EnteraBio is due promptly after Amgen determines such achievement has occurred, and EnteraBio shall invoice Amgen for the applicable Milestone Payment. Amgen will pay each such invoice within forty-five (45) days of its receipt thereof.

Section 7.3 Royalties.

7.3.1 Royalties. Subject to the provisions of this Section 7.3 and Section 3.8, Amgen shall pay to EnteraBio, with respect to Products, on a Product-by-Product and country-by-country basis, royalties on annual Net Sales of Products during the applicable Royalty Term, calculated as set forth in Section 7.3.3. Royalties will be payable on a calendar quarterly basis and any such payments shall be made within [*] after the end of the calendar quarter during which the applicable Net Sales of Products occurred.

7.3.2 Royalty Term. Amgen's obligation to pay royalties with respect to a Product in a particular country shall commence upon the First Commercial Sale of such Product in such country and shall expire on a country-by-country and Product-by-Product basis on the later of (a) the date on which the sale of the Product is no longer Covered by a Valid Claim of an EnteraBio Patent or Collaboration Patent, and (b) the tenth (10th) anniversary of the First Commercial Sale of such Product in such country (the "**Royalty Term**").

7.3.3 Royalty Rates. The royalty rates payable under Section 7.3.1 shall be calculated as follows:

Aggregate Annual Net Sales of Products under a Collaboration Program	Royalty Rate
(a) With respect to the Initial Program: commencing on the first year in which aggregate annual Net Sales of Products under the Initial Program is greater than or equal to [*], for aggregate annual Net Sales of Products less than [*]; and (b) With respect to each Post-Effective Date Program: for aggregate annual Net Sales of Products less than [*].	[*]
If aggregate annual Net Sales of Products under a Collaboration Program is greater than or equal to [*] and less than [*]	[*]

If aggregate annual Net Sales of Products under a Collaboration Program greater than or equal to [*]

[*]

For the avoidance of doubt, if the sale of a Product is Covered by more than one Valid Claim, the above royalty shall be paid only once.

7.3.4 Royalty Reduction.

(a) On a country-by-country and Product-by-Product basis, in the event that (i) the Exploitation of a Product is not Covered by a Valid Claim of an EnteraBio Patent or Collaboration Patent in such country and the Royalty Term for such Product in such country has not expired, and (ii) a Third Party commences commercial sale of a Generic Version of a Product in a country, then the royalty rates set forth in Section 7.3.3 with respect to Net Sales for such Product in such country shall be reduced by [*], effective as of the later of: (x) the date such Product is no longer Covered by a Valid Claim of an EnteraBio Patent or Collaboration Patent in such country; and (y) the first day of the first calendar quarter following the calendar quarter in which Net Sales of such Product in the applicable country decrease by more than[*] from the Net Sales of such Product in such country in the calendar quarter immediately preceding the first commercial sale of such Generic Version.

7.3.5 Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts required hereunder.

Section 7.4 Invoicing. To the extent an invoice is required to be submitted to Amgen hereunder, such invoice shall be addressed to:

Amgen Inc.
Accounts Payable
PO Box 667
Newbury Park, CA 91319-0667
Attention: [*]

Section 7.5 Method of Payment. Unless otherwise agreed by the Parties, all payments due from Amgen under this Agreement shall be paid by wire transfer or electronic funds transfer of immediately available funds to an account designated in writing by EnteraBio. After the First Commercial Sale of the first Product and until expiration of the last Royalty Term for a Product, Amgen shall prepare and deliver to EnteraBio reports of the sale of Products by the Selling Parties for each calendar quarter together with the corresponding royalty payment or other consideration to be paid to EnteraBio in accordance with Section 7.3.1, specifying on a Product-by-Product and country-by-country basis, a detailed and itemized calculation of Net Sales in a manner that is consistent with the method generally used by the Amgen Finance Department to track such information for Amgen's other commercialized products in the Territory.

Section 7.6 Currency Conversion. All royalties shall be payable in full in U.S. Dollars. Any sales of Products incurred in a currency other than U.S. Dollars shall be converted to the U.S. Dollar equivalent using Amgen's then-current standard exchange rate methodology as applied to its external reporting for the conversion of foreign currency sales into U.S. Dollars.

Section 7.7 Records and Audits. The Parties shall keep complete and accurate records of payments required under this Agreement for a period of [*] after the end of the calendar year in which any such payment was due. Each Party will have the right, [*] annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to the other Party's prior written consent (which shall not be unreasonably withheld, conditioned or delayed), review any such records of such other Party and its Affiliates and their Sublicensees upon reasonable written notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement for the period under audit. No calendar year will be subject to audit under this Section 7.7 more than once. The audited Party will receive a copy of each such report concurrently with receipt by the auditing Party, and such accounting firm shall report to the Parties whether or not such calculations are correct and the amount of any discrepancy. Each Party agrees to treat the results of any such review of the audited Party's and its Affiliates' records under this Section 7.7 as Confidential Information of the audited Party and subject to the terms of Article 12. Should such inspection lead to the discovery of a discrepancy to either EnteraBio's or Amgen's detriment, the other Party will promptly pay EnteraBio or Amgen, as applicable, any undisputed amount of the discrepancy together with interest at the rate set forth in Section 7.8. If an audit reveals an underpayment of more than the greater of [*] of the amount that should have been paid to EnteraBio during the audited period, Amgen shall bear the full expenses of the audit.

Section 7.8 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of [*] the prime interest rate quoted by *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com on the date said payment is due, the interest being compounded on the last day of each calendar quarter; *provided, however*, that in no event shall said annual interest rate exceed the maximum rate permitted by Law. Each such payment when made shall be accompanied by all interest so accrued. With respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

Section 7.9 Taxes.

7.9.1 Withholding. In the event that any Law requires Amgen to withhold taxes with respect to any payment to be made by Amgen pursuant to this Agreement, Amgen will notify EnteraBio of such withholding requirement prior to making the payment to EnteraBio and provide such assistance to EnteraBio, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in EnteraBio's efforts to claim an exemption from or reduction of such

taxes. Amgen will, in accordance with such Law, withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish EnteraBio with proof of payment of such taxes within thirty (30) days following the payment. If taxes are paid to a tax authority, Amgen shall provide reasonable assistance to EnteraBio to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. If any taxes are so withheld, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to EnteraBio. EnteraBio shall provide Amgen any tax forms (including Internal Revenue Service Form W-8BEN or W-8ECI or other applicable Internal Revenue Service Form) that may be reasonably necessary in order for Amgen to determine whether to withhold tax on any such payments or to withhold tax on such payments at a reduced rate under applicable tax Law, including any applicable bilateral income tax treaty.

7.9.2 **VAT.** All payments due to EnteraBio from Amgen pursuant to this Agreement shall be paid exclusive of any value-added tax (“VAT”) (which, if applicable, shall be payable by Amgen upon receipt of a valid VAT invoice). If EnteraBio determines that it is required to report any such tax, Amgen shall promptly provide EnteraBio with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 7.9.2 is not intended to limit Amgen’s right to deduct value-added taxes in determining Net Sales.

ARTICLE 8. INTELLECTUAL PROPERTY

Section 8.1 Intellectual Property Ownership.

8.1.1 **Background IP.** Each Party will own all right, title and interest in its Background IP.

8.1.2 **Collaboration IP.** Ownership of Collaboration IP shall follow inventorship. Inventorship will be determined according to U.S. Patent Law (without reference to any conflict of law principles). Amgen, on behalf of itself and its Affiliates and Sublicensees, hereby grants and agrees to grant to EnteraBio a fully paid up, perpetual, worldwide, non-exclusive license, with a right to grant sublicenses, under Collaboration IP solely owned by Amgen, its Affiliates and Sublicensees, solely to the extent such Collaboration IP claims an Improvement to the EnteraBio Platform, to Exploit such Improvement to the EnteraBio Platform for all purposes, subject to the exclusivity granted to Amgen under this Agreement.

8.1.3 **Joint IP.** Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit inventions or intellectual property owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 8.1.3 in a particular country within the Territory. Notwithstanding the foregoing, Amgen shall retain all rights to the antibody nucleic acid sequences provided to EnteraBio under this Agreement, along with the polypeptide sequences, and nucleic acids encoded by such said nucleic acid sequences, Derivatives of said polypeptide sequences and nucleic acids encoding said Derivatives. “**Derivatives**” shall include [*].

Section 8.2 Patent Prosecution and Maintenance.

8.2.1 EnteraBio Patent(s). Other than with respect to any Collaboration Patents, EnteraBio will be solely responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all EnteraBio Patents and conducting any interferences and oppositions or similar proceedings relating to EnteraBio Patents. Amgen acknowledges and agrees that (a) neither EnteraBio nor any of its Affiliates will have any liability of any kind relating to the preparation, filing, prosecution and maintenance of Patent Rights as provided in this Section 8.2.1; and (b) EnteraBio and its Affiliates have the right to cease all activities relating to the preparation, filing, prosecution or maintenance of any Patent Rights as provided in this Section 8.2.1 for any reason, in which case EnteraBio will promptly inform Amgen of such planned cessation.

8.2.2 Amgen Patent(s). Other than with respect to any Collaboration Patents, Amgen will be solely responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all Amgen Patents and conducting any interferences and oppositions or similar proceedings relating to Amgen Patents. EnteraBio acknowledges and agrees that (a) neither Amgen nor any of its Affiliates will have any liability of any kind relating to the preparation, filing, prosecution and maintenance of Patent Rights as provided in this Section 8.2.2; and (b) Amgen and its Affiliates have the right to cease all activities relating to the preparation, filing, prosecution or maintenance of any Patent Rights as provided in this Section 8.2.2 for any reason, in which case Amgen will promptly inform EnteraBio of such planned cessation.

8.2.3 Collaboration Patents. EnteraBio will be primarily responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all Patent Rights constituting Collaboration Patents that: (i) solely claim Improvements to the EnteraBio Platform; or (ii) solely claim Collaboration Know-How generated solely by EnteraBio after the applicable Preclinical R&D Term or (iii) pursuant to Section 8.1.2 are owned solely by EnteraBio (the “**EnteraBio Prosecuted Collaboration Patents**”), and conducting any interferences and oppositions or similar proceedings relating to such Patent Rights. Other than the EnteraBio Prosecuted Collaboration Patents, Amgen will be primarily responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all other Patent Rights constituting Collaboration Patents and conducting any interferences and oppositions or similar proceedings relating to such Patent Rights. The filing Party will provide the non-filing Party with copies of and an opportunity to review and comment upon the text of the applications relating to the applicable Collaboration Patents at least thirty (30) days before filing; *provided, however*, that if it is not reasonably practicable to provide such application in such thirty (30) day period, then the filing Party will provide either a draft copy of such application or a statement of intent to file such application in such thirty (30) day period. The filing Party will provide the non-filing Party with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Collaboration Patent reasonably promptly after making such filing or receiving such document, including a copy of each application for each Collaboration Patent as filed together with notice of its filing date and application number. The filing Party will keep the non-filing Party advised of the status of all material communications, and actual and prospective filings or

submissions regarding the Collaboration Patents, and will give the non-filing Party copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body. The filing Party will consider in good faith the non-filing Party's comments on such communications, filings and submissions for the Collaboration Patents. With respect to any filings or other materials provided to the non-filing Party under this Section 8.2.3, the filing Party will have the right to redact information relating to manufacturing, CMC or devices, any product other than Products or any Know-How other than Collaboration Know-How from any such filings and materials. In the event either Party declines to file, prosecute or maintain any of the foregoing Patent Rights, elects to allow any Patent Rights to lapse in any country, or elects to abandon any Patent Rights (in each case to the extent contained in the Collaboration Patents) before all appeals within the respective patent office have been exhausted (each, an "**Abandoned Patent Right**"), then: (1) such Party shall provide the other Party with reasonable notice of such decision so as to permit the non-abandoning Party to decide whether to file, prosecute or maintain such Abandoned Patent Rights and to take any necessary action (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office or any foreign patent office); (2) the non-abandoning Party, at the non-abandoning Party's expense, may assume control of the filing, prosecution or maintenance of such Abandoned Patent Rights; (3) the non-abandoning Party shall have the right, at its expense, to transfer the responsibility for such filing, prosecution and maintenance of such Abandoned Patent Rights to patent counsel (outside or internal) selected by the non-abandoning Party; and (4) the abandoning Party shall, at the non-abandoning Party's reasonable request and at the non-abandoning Party's expense, assist and cooperate in the filing, prosecution and maintenance of such Abandoned Patent Rights.

Section 8.3 Patent Term Extensions. The Parties will cooperate with each other in gaining Patent Right term extension where applicable to Products, and in the case of any disagreement, Amgen shall have the final say as to term extension for any Patent Right claiming the composition of matter or method of use of a Product.

Section 8.4 Defense and Settlement of Third Party Claims. If either (a) any Product Exploited by or under authority of either Party becomes the subject of a Third Party's claim or assertion of infringement of a patent, or (b) a declaratory judgment action is brought naming either Party as a defendant and alleging invalidity of any of the Patent Rights contained in Collaboration Patents, EnteraBio Patents or Amgen Patents, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). Neither Party shall enter into any settlement of any claim described in this Section 8.4 that admits to the invalidity or unenforceability of any Patent Right Controlled by the other Party or jointly by the Parties (or otherwise affects the scope, validity or enforceability of such Patent Right), incurs any financial liability on the part of any other Party or requires an admission of liability, wrongdoing or fault on the part of the other Party without such other Party's written consent. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's request and expense. Additionally, if the Defending Party is not the Party that Controls the Patent Right in question, then the other Party has the right to join any such action.

Section 8.5 Enforcement.

8.5.1 Notice of Infringement. The Parties shall inform each other promptly of any infringement or colorable cause of action for infringement of any Patent Right within the Collaboration Patents, EnteraBio Patents or Amgen Patents, and the Parties shall promptly confer to consider the best appropriate course of action.

8.5.2 Enforcement. In the event that such infringement or alleged infringement is with respect to a product that has the same primary mechanism of action as a Product, then Amgen shall have the right to enforce the following Patent Rights against any such infringement or alleged infringement thereof: with respect to (a) an Amgen Patent, such right shall be a sole right and shall not require the prior written consent of EnteraBio, (b) EnteraBio Patents or Collaboration Patents which constitute an Improvement of the EnteraBio Platform, such right shall require the prior written consent of EnteraBio, and (c) any Patent Right within the Collaboration Patents, other than the aforementioned, such right shall be a sole right and shall not require the prior written consent of EnteraBio. Amgen shall at all times keep EnteraBio informed as to the status thereof. In such case, Amgen may, at its own expense, institute suit against any infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 8.5.5. EnteraBio shall reasonably cooperate in any such litigation at Amgen's expense. [*]. In the event that Amgen does not elect to enforce any Patent Right within the EnteraBio Patents or Collaboration Patents, then EnteraBio shall be entitled to do so, [*].

8.5.3 Progress Reporting. The Party initiating or defending any such enforcement action (the "Enforcing Party") shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the individual right to participate with counsel of its own choice at its own expense.

8.5.4 Allocation of Recoveries. [*]

[*]

[*]

Section 8.6 Trademarks. As between the Parties, Amgen shall own all right, title and interest in and to any trademarks adopted by Amgen for use with a Product, and shall be responsible for the registration, filing, maintenance and enforcement thereof.

ARTICLE 9. REPRESENTATIONS, WARRANTIES AND COVENANTS

Section 9.1 Mutual Representations and Warranties. Each of Amgen and EnteraBio represents and warrants to the other Party, as of the Effective Date, that:

- (a) it is duly incorporated and validly existing under, with respect to Amgen, the Law of Delaware, and with respect to EnteraBio, the Law of the State of Israel, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; and
- (c) this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (x) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any material applicable Law or (y) require any consent or approval of its stockholders or similar action.

Section 9.2 Additional EnteraBio Representations, Warranties and Covenants. EnteraBio represents and warrants to Amgen that, as of the Effective Date (except as specifically stated otherwise):

- (a) EnteraBio has full legal or beneficial title and ownership of, or an exclusive license to, the EnteraBio Patents as is necessary to grant the licenses (or sublicenses) to Amgen to such EnteraBio Patents that EnteraBio purports to grant pursuant to this Agreement;
- (b) EnteraBio has the rights necessary to grant the licenses to Amgen under EnteraBio Licensed Know-How that EnteraBio purports to grant pursuant to this Agreement;
- (c) To EnteraBio's knowledge, the EnteraBio Patents licensed to EnteraBio and its Affiliates are not subject to, any liens or encumbrances, and EnteraBio has not, and will not during the Term, grant any right to any Third Party under or with respect to the EnteraBio IP that would conflict with the rights granted to Amgen hereunder or terminate any rights granted by a Third Party to EnteraBio or its Affiliates that are further granted to Amgen hereunder;
- (d) Except as disclosed in EnteraBio's SEC filings, no claim or action has been brought or, to EnteraBio's knowledge, threatened by any Third Party alleging that (i) the EnteraBio Patents are invalid or unenforceable or (ii) use of the EnteraBio IP infringes or misappropriates or would infringe or misappropriate any right of any Third Party, and no EnteraBio Patent is the subject of any interference, opposition, cancellation or other protest proceeding. EnteraBio has not received any written notice from any Third Party asserting or alleging that the development, manufacture, use or sale of any Product infringes the rights of such Third Party in the Territory;
- (e) There are no pending actions, claims, investigations, suits or proceedings against EnteraBio or its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither EnteraBio nor any of its Affiliates has received any written notice regarding any pending or threatened

actions, claims, investigations, suits or proceedings against EnteraBio or such Affiliate, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the EnteraBio IP; and

(f) To EnteraBio's knowledge, no Third Party, including any current or former employee or consultant of EnteraBio, is infringing or misappropriating or has infringed or misappropriated the EnteraBio IP.

Section 9.3 Additional Amgen Representations, Warranties and Covenants. Amgen represents and warrants to EnteraBio that, as of the Effective Date (except as specifically stated otherwise):

(a) Amgen has full legal or beneficial title and ownership of, or an exclusive license to, the Amgen Patents as is necessary to grant the licenses (or sublicenses) to EnteraBio to such Amgen Patents that Amgen purports to grant pursuant to this Agreement;

(b) The Amgen Patents owned by Amgen and its Affiliates are not subject to, and to Amgen's knowledge the Amgen Patents licensed to Amgen and its Affiliates are not subject to, any liens or encumbrances and Amgen has not granted to any Third Party any rights or licenses under such Patent Rights that would conflict with the licenses granted to EnteraBio hereunder;

(c) Amgen has no knowledge of any claim or litigation that has been brought or threatened in writing by any Third Party alleging that (i) the Amgen Patents are invalid or unenforceable or (ii) the use of the Amgen IP infringes or misappropriates or would infringe or misappropriate any right of any Third Party, and no Amgen Patent is the subject of any interference, opposition, cancellation or other protest proceeding.

Section 9.4 Mutual Covenants.

(a) **Employees, Consultants and Contractors.** Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform research or development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign inventions in a manner consistent with the provisions of this Agreement.

(b) **Debarment.** Each Party represents, warrants and covenants to the other Party that it is not debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings under the U.S. Food, Drug and Cosmetic Act or comparable Laws in any country or jurisdiction other than the U.S. and, to its knowledge, does not, and will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates or Sublicensees, the services of any person who is debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings in connection with activities relating to any Product. In the event that either Party becomes aware of the debarment, exclusion or disqualification or threatened debarment, exclusion or disqualification of any person providing services to such Party, directly or indirectly, including through Affiliates or Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) **Compliance.**

(i) Each Party agrees, on behalf of itself and its officers, directors, employees, Affiliates and agents, that, in connection with the matters that are the subject of this Agreement, and the performance of its obligations hereunder:

- (a) It shall use its commercially reasonable efforts to comply with all applicable (i) U.S. Laws prohibiting the re-export, directly or indirectly, of certain controlled U.S.-origin items without a license to parties located in certain countries or appearing on certain U.S. Government lists of restricted parties; (ii) U.S. Laws prohibiting participation in non-U.S. boycotts that the United States does not support; (iii) U.S. Laws prohibiting the sale of products to parties from any country subject to U.S. economic sanctions or who are identified on related U.S. Government lists of restricted parties; and (iv) data privacy laws of the applicable jurisdiction, including the national and sub-national laws based on the European Union Data Protection Directive 95/46/EC, and all data breach notification and information securities laws and regulations specific thereto.
- (b) It will comply with the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable Law relating to or concerning public or commercial bribery or corruption (collectively, “**Anti-Bribery and Anti-Corruption Laws**”) and its applicable anti-corruption policies (“**Anti-Corruption Policies**”), and will not take any action that will cause the other Party or its Affiliates to be in violation of any such laws or policies.
- (c) It will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give or authorize the giving of anything of value to any Public Official or Entity for the purpose of influencing the acts of such Public Official or Entity to induce them to use their influence with any Governmental Authority, or obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Anti-Bribery and Anti-Corruption Laws or Anti-Corruption Policies.
- (d) It will not directly or indirectly solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Bribery and Anti-Corruption Laws or the Anti-Corruption Policies.

(ii) Each Party, on behalf of itself and its officers, directors, employees, Affiliates, agents and Representatives, represents and warrants to the other Party that, in connection with the matters that are the subject of this Agreement, and the performance by each Party of its obligations hereunder:

- (a) To its knowledge, as of the Effective Date, it and its Affiliates have not committed any Material Anti-Corruption Law Violation, other than, in the case of Amgen, the mis-promotion activities preceding the Corporate Integrity Agreement, entered into between Amgen and the Office of the Inspector General of the Department of Health and Human Services in December 2012.

(b) To its knowledge, none of its contracts, licenses or other assets that are the subject of this Agreement were procured in violation of the Anti-Bribery and Anti-Corruption Laws.

(iii) Each Party will keep and maintain accurate books, accounts, invoices and reasonably detailed records in connection with the performance of its obligations under, and payments made in connection with, this Agreement, including all records required to establish compliance with the provisions of this Section 9.4(c), until the later of (a) [*] after the end of the period to which such books and records pertain or (b) the expiration of the applicable statute of limitations (or any extension thereof).

(iv) If a Party becomes aware that any of its officers, directors or employees becomes during the Term a Public Official or Entity in a position to take or influence official action for or against a Party in connection with the performance of its obligations under this Agreement, that Party will promptly notify the other Party. A Party shall notify the other Party upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its representatives that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation in connection, in either case in connection with this Agreement.

(v) If either Party requests that any other Party complete a compliance certification certifying compliance with this Section 9.4(c), which request shall occur no more than [*] per calendar year, such other Party shall promptly complete and deliver such compliance certification truthfully and accurately. If either Party requests, in connection with a Corporate Integrity Agreement or similar arrangement with a Governmental Authority, that any other Party complete a compliance certification certifying adherence to and compliance with such other Party's code of conduct and compliance program with respect to such other Party's activities under this Agreement, which request shall occur no more than [*] per calendar year, such other Party shall cooperate with the first Party to promptly complete and deliver such compliance certification truthfully and accurately, and should there be reasonable additional requests of such other Party as a result of a Corporate Integrity Agreement or similar arrangement with a Governmental Authority of the requesting Party, such other Party shall comply with such requests at the requesting Party's cost and expense.

(vi) In the event that a Party has a good faith reason to believe that the other Party may be in breach or violation of any representation, warranty or undertaking in this Section 9.4(c), such Party shall have the right to conduct an examination and audit of relevant books and records of the other Party and, during the pendency of such examination, to suspend any obligations on the part of such Party to the other Party. In the event that a Party becomes aware, whether or not through audit, that the other Party is in breach of or in violation of any representation, warranty or undertaking in this Section 9.4(c), then that Party shall have the right to take such steps as are reasonably necessary in order to avoid a violation or continuing violation of the Anti-Bribery and Anti-Corruption Laws, including by requesting such additional representations, warranties, undertakings and other provisions including a further audit as it believes in good faith are reasonably necessary.

Section 9.5 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENT RIGHTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE PRODUCTS WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

ARTICLE 10. INDEMNIFICATION

Section 10.1 Indemnity.

10.1.1 By EnteraBio. EnteraBio agrees to defend Amgen, its Affiliates, and each of their respective directors, officers, employees and agents (the “Amgen Indemnified Parties”), at EnteraBio’s cost and expense, and will indemnify and hold Amgen and the other Amgen Indemnified Parties harmless from and against any claims, losses, costs, damages, fees or expenses (including reasonable legal fees and expenses) (collectively, “Losses”) to the extent resulting from any claims, actions, suits or proceedings brought by a Third Party (including product liability claims) (a “Third Party Claim”) arising out of (a) the gross negligence or willful misconduct of EnteraBio, its Affiliates or their respective Sublicensees in connection with its activities under this Agreement; (b) the material breach of this Agreement or the representations, warranties and covenants made hereunder by EnteraBio, (c) the material breach by EnteraBio or its Affiliates of any agreement or arrangement with a subcontractor performing its obligations under this Agreement pursuant to Section 3.2, and (d) other matters that the Parties agree to in writing; except, in each case, to the extent such Losses result from clause (a), (b), or (c) of Section 10.1.2.

10.1.2 By Amgen. Amgen agrees to defend EnteraBio, its Affiliates and their respective directors, officers, employees and agents (the “EnteraBio Indemnified Parties”), at Amgen’s cost and expense, and will indemnify and hold EnteraBio and the other EnteraBio Indemnified Parties harmless from and against any Losses to the extent resulting from any Third Party Claims arising out of (a) the gross negligence or willful misconduct of Amgen, its Affiliates, or their respective Sublicensees in connection with its activities under this Agreement; (b) the material breach of this Agreement or the representations, warranties and covenants made hereunder by Amgen; (c) the material breach by Amgen or its Affiliates of any agreement or arrangement with a subcontractor performing its obligations under this Agreement pursuant to Section 3.2, and or (d) the research, development, manufacture or other Exploitation of any Product by or on behalf of Amgen, its Affiliates, or their respective Sublicensees (including from product liability and intellectual property infringement claims); except, in each case, to the extent such Losses result from clause (a), (b), (c) or (d) of Section 10.1.1.

10.1.3 Procedure. The foregoing indemnity obligations shall be conditioned upon (x) the indemnified Party (“Indemnitee”) promptly notifying the indemnifying Party (“Indemnitor”) in writing of the assertion or the commencement of the relevant Third Party Claim (*provided, however*, that any failure or delay to notify shall not excuse any obligation of the Indemnitor, except to the extent the Indemnitor is actually prejudiced thereby), (y) the Indemnitee granting the Indemnitor sole management and control, at the Indemnitor’s sole expense, of the defense of such Third Party Claim and its settlement

(provided, however, that the Indemnitor shall not settle any such Third Party Claim without the prior written consent of the Indemnitee if such settlement does not include a complete release from liability or if such settlement would involve the Indemnitee undertaking an obligation (including the payment of money by the Indemnitee), would bind or impair the Indemnitee, or includes any admission of wrongdoing by the Indemnitee or that any intellectual property or proprietary right of Indemnitee or this Agreement is invalid, narrowed in scope or unenforceable, and (z) the Indemnitee reasonably cooperating with the Indemnitor (at the Indemnitee's expense). The Indemnitee shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. Notwithstanding the foregoing, the Indemnitee will have the right to employ separate counsel at the Indemnitee's expense and to control its own defense of the applicable Third Party Claim only if: (i) there are or may be legal defenses available to the Indemnitee that are different from or additional to those available to the Indemnitor or (ii) in the reasonable opinion of counsel to the Indemnitee, a conflict or potential conflict exists between the Indemnitee and the Indemnitor that would make such separate representation advisable. The Indemnitee shall not settle or compromise such Third Party claim without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld, conditioned or delayed.

ARTICLE 11. LIMITATIONS OF LIABILITY

Section 11.1 LIMITATION OF DAMAGES. IN NO EVENT SHALL A PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 11.1 SHALL NOT APPLY WITH RESPECT TO ANY BREACH OF ARTICLE 12. NOTHING IN THIS SECTION 11.1 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER ARTICLE 10 WITH RESPECT TO ANY DAMAGES REQUIRED TO BE PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM.

Section 11.2 Insurance. Each of the Parties will, at their own respective expense procure and maintain during the Term and for [*] thereafter, insurance policies adequate to cover their obligations hereunder and consistent with the normal business practices of prudent biopharmaceutical companies of similar size and scope (or reasonable self-insurance sufficient to provide materially the same level and type of protection), and will upon request provide the other Party with a certificate of insurance in that regard, along with any amendments and revisions thereto. Such insurance will not create a limit to either Party's liability hereunder.

ARTICLE 12. CONFIDENTIALITY

Section 12.1 Confidential Information.

12.1.1 Confidential Information. Each Party (the "Receiving Party") may receive during the course and conduct of activities under this Agreement, certain proprietary or confidential information of the other Party (the "Disclosing Party") as furnished to the Receiving Party by or on behalf of the Disclosing Party. The term "Confidential Information" means all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party or at the request of Receiving Party, including any of the foregoing of Affiliates or Third Parties.

12.1.2 Restrictions. During the Term and for [*] thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). Receiving Party will not use Disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. For clarity, Amgen shall have the right to use any Confidential Information of EnteraBio in the Exploitation of a Product. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are bound by restrictions on use and disclosure consistent with this Section 12.1.2. Receiving Party will use diligent efforts to cause those entities and persons to comply with the restrictions on use and disclosure in this Section 12.1.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

12.1.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (a) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by Disclosing Party hereunder; (b) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (c) is obtained by Receiving Party or any of its Affiliates from a Third Party not known by the Receiving Party after reasonable inquiry to be under an obligation of confidentiality to Disclosing Party; (d) has been independently discovered or developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the reference to or use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records; or (e) was released from the restrictions set forth in this Agreement by express prior written consent of the Disclosing Party.

12.1.4 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

- (a) in order to comply with applicable Law (including any securities law or regulation or the rules of a securities exchange or as a requirement in filing for an International Nonproprietary Name (INN) or the like) or with a legal or administrative proceeding, or in connection with prosecuting or defending litigation;
- (b) in connection with prosecuting and defending litigation, Marketing Approvals and other Regulatory Filings and communications, and filing, prosecuting and enforcing Patent Rights in connection with Receiving Party's rights and obligations pursuant to this Agreement; and
- (c) [*]; permitted acquirers or assignees; and investment bankers, investors and lenders;

provided, however, that (1) with respect to each of Sections 12.1.4(a) and 12.1.4(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed; and (2) with respect to Section 12.1.4(c), [*].

Section 12.2 Terms of this Agreement; Publicity.

12.2.1 Restrictions. The Parties agree that the terms of this Agreement, including the identity of each Collaboration Program, will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 12.1.4. Except as required by Law or as permitted under Section 12.1.4, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed (or as such consent may need to be obtained in accordance with Section 12.3). Notwithstanding the foregoing, a press release in the form attached hereto as Exhibit D shall be issued by EnteraBio on or as promptly as practicable after the Effective Date.

12.2.2 Review. Subject to Section 12.1.4, in the event either Party (the "**Issuing Party**") desires to issue a press release (other than as set forth on Exhibit D) or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "**Reviewing Party**") with a copy of the proposed press release or public statement (the "**Release**"). The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release (but in no event less than ten (10) business days). If the Reviewing Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release, provided that (a) the other Party provided its written consent hereto as stated in Section 12.2.1, and (b) circumstances have not changed such that such previous disclosure is rendered inaccurate or misleading. For the avoidance of doubt (and notwithstanding anything contained in this Agreement to the contrary), Amgen, in its sole discretion, may make disclosures relating to the development or commercialization of a Product, including the results of research and any clinical trial conducted by Amgen or any health or safety matter related to a Product.

Section 12.3 Publication. Amgen will have the sole right to publish and make scientific presentations with respect to Products, and to issue press releases (except with respect to the terms of this Agreement, which is governed by Section 12.2) or make other public disclosures regarding any such Products, and EnteraBio will not do so without Amgen's prior written consent, except as required by Law; *provided, however*, that any publication or presentation to be made by Amgen that names EnteraBio will require the prior written consent of EnteraBio. The Party that is entitled hereunder to make a publication or presentation (the "**Publishing Party**") will deliver to the other Party (the "**Non-Publishing Party**") a copy of any proposed written publication or outline of presentation

to be made by the Publishing Party in advance of submission for publication or presentation at least thirty (30) days in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and the Non-Publishing Party will have the right to: (a) require a delay in submission of not more than sixty (60) days to enable patent applications protecting any product; and (b) prohibit disclosure of any of its Confidential Information in any such proposed publication or presentation. If there is any dispute between the Parties with regard to a proposed publication, presentation or other communication regarding this Agreement, such dispute shall be referred to the JRC for resolution. Each Party agrees that it will not unreasonably withhold, condition or delay its consent to requests for (i) extensions of the above timelines in the event that material late-breaking clinical data becomes available or (ii) shortening of the above timelines if the requesting Party has a good faith belief that circumstances warrant such acceleration. The Parties acknowledge and agree that all publications and presentations pursuant to this Section 12.3 shall comply with the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Consistent with those guidelines, authorship will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any publication(s) derived from this Agreement, and authors must engage in the drafting of the publication or revise it critically for important intellectual content. Each party agrees to maintain evidence of its compliance with the ICMJE guidelines for authorship, and that it will provide such evidence to the other Party upon request.

Section 12.4 Relationship to the Confidentiality Agreement. This Agreement supersedes the Confidential Disclosure Agreement; *provided, however*, that all “Confidential Information” disclosed or received by the Parties thereunder will be deemed “Confidential Information” hereunder and will be subject to the terms and conditions of this Agreement.

Section 12.5 Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

ARTICLE 13. TERM & TERMINATION

Section 13.1 Term. The term of this Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 13 or Section 4.5.2, shall continue in full force and effect, on a Product-by-Product basis, until expiration of the last-to-expire Royalty Term with respect to such Product (the “**Term**”). On a country-by-country and Product-by-Product basis, the licenses granted under this Agreement to Exploit all Products to a terminated Collaboration Program shall be fully paid-up, irrevocable and non-exclusive upon the expiration of the Royalty Term in each country applicable to each such Product.

Section 13.2 Termination by EnteraBio.

13.2.1 Amgen Breach. EnteraBio will have the right to terminate this Agreement in the event of any material breach by Amgen of any terms and conditions of this Agreement; *provided, however*, that such termination will not be effective if such breach has been cured within ninety (90) days after written notice thereof is given by EnteraBio to Amgen specifying the nature of the alleged breach. Notwithstanding the foregoing in this Section 13.2.1, in the event of a good faith dispute as to whether performance has been made by either Party pursuant to this Agreement, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided, however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

Section 13.3 Termination by Amgen.

13.3.1 EnteraBio Breach Amgen will have the right to terminate this Agreement in the event of any material breach by EnteraBio of any terms and conditions of this Agreement; *provided, however*, that such termination will not be effective if such breach has been cured within ninety (90) days after written notice thereof is given by Amgen to EnteraBio specifying the nature of the alleged breach. . Notwithstanding the foregoing in this Section 13.3.1, in the event of a good faith dispute as to whether performance has been made by either Party pursuant to this Agreement, including any good faith dispute as to any payment due under this Agreement, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided, however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

13.3.2 Discretionary Termination. [*]

Section 13.4 Effects of Termination. Upon termination by a Party, as applicable, under Section 4.5.2, Section 13.2 or Section 13.3 (provided that, to the extent this Agreement is terminated solely with respect to a particular Collaboration Program or Product, then the remainder of this Section 13.4 shall only apply to the terminated Collaboration Program or Product):

13.4.1 Ongoing Clinical Studies. The Termination Party will responsibly wind-down, in accordance with accepted biopharmaceutical industry norms and ethical practices, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced, and Amgen will be responsible for any costs and expenses reasonably associated with or actually incurred with such wind-down.

13.4.2 Termination of Licenses and Sublicense. All relevant licenses and sublicenses granted under Article 4, as of the effective date of such termination, shall terminate automatically unless otherwise agreed by the Parties in writing.

13.4.3 Destruction of Confidential Information. Each Party shall destroy, at the other Party's request, Confidential Information that it has received from such other Party and is in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement); provided that each Party may retain and continue to use all such Confidential Information of the other Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Notwithstanding the foregoing, a Party shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its employees, consultants, or others who received Confidential Information under this Agreement.

13.4.4 Prior Payments. Each Party shall pay all undisputed amounts then due and owing to the other Party as of the termination date. In addition, Amgen shall pay EnteraBio all non-cancelable expenses and costs EnteraBio is obliged to pay and which are to be reimbursed according to Section 3.1.

Section 13.5 Survival. In addition to the expiration or termination consequences set forth in Section 13.4 and the provisions that are expressly stated to survive termination, the following provisions will survive termination or expiration of this Agreement: Articles 1, 10, 11 and 14, Section 7.2 (with respect to a Milestone Events reached prior to such expiration or termination), Section 7.3 (with respect to sales made before such expiration or termination), Sections 7.4 through 7.9 inclusive (with respect to periods with sales of Products made before such expiration or termination), Section 8.1, Sections 8.4 and 8.5 (with respect to any action initiated prior to such expiration or termination), Sections 9.5, 12.1, 12.2, 12.3 (with respect to any paper or presentation proposed, or any paper or presentation including data or results of clinical studies conducted, prior to such expiration or termination), 12.4, 12.5 (solely the first sentence) 13.4 and 13.5. Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon termination or expiration of this Agreement.

ARTICLE 14. MISCELLANEOUS

Section 14.1 Entire Agreement; Amendment. This Agreement and all Exhibits attached hereto constitute the entire agreement between the Parties as to the subject matter hereof. All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement, including the Confidential Disclosure Agreement, are hereby superseded and merged into, extinguished by and completely expressed by this Agreement. Neither of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by Amgen and EnteraBio.

Section 14.2 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 14.3 Independent Contractors. The relationship between Amgen and EnteraBio created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. No such Party is a legal representative of the other Party, and no such Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each such Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

Section 14.4 Governing Law; Disputes. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Amgen Patent, EnteraBio Patent or Collaboration Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued. If a dispute regarding this Agreement or the activities contemplated hereby arises between the Parties, the Parties shall attempt to solve the issue through good faith discussions for a period of at least sixty (60) days, and the Parties will use reasonable efforts to reach an amicable resolution of the issue during such period. During such sixty (60)-day period, the Parties may agree to submit such dispute for non-binding mediation. If, notwithstanding the efforts of the Parties in accordance with the previous sentence, after such sixty (60)-day period, a dispute cannot be amicably resolved, then such dispute shall be finally settled under the Rules of Arbitration of the International Institute for Conflict Prevention and Resolution by [*] arbitrators, of whom each Party shall designate [*], with the [*] arbitrator to be designated by the [*] Party-appointed arbitrators. Such arbitration shall be conducted in New York, NY, U.S.A. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §1 et seq., and judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof. The arbitrator shall not have the power to grant any award or remedy other than such awards or remedies that are available under the applicable Law. Notwithstanding the foregoing, each Party understands and agrees that a Party shall be entitled to seek injunctive and/or equitable relief and enforcement of any arbitration award from the applicable courts in any appropriate jurisdiction.

Section 14.5 Notice. Any notice required or permitted to be given by this Agreement shall be in writing, in English. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective if (a) delivered by hand or by overnight courier with tracking capabilities, (b) mailed postage prepaid by first class, registered, or certified mail, or (c) delivered by facsimile followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section 14.5, in each case, addressed as set forth below unless changed by notice so given:

If to EnteraBio: EnteraBio Ltd.
Minrav Building, 5th Floor, PO Box 12117
Jerusalem 91220
Israel
Attn: Philip Schwartz, CEO

with a copy (which shall not constitute notice) to:

Herzog, Fox & Neeman
Asia House, 4 Weizmann St.
Tel Aviv 6423904
Israel
Attn: Yair Geva, Adv. and Tomer Farkash, Adv.

If to Amgen: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320
USA
Attn: [*]

with a copy (which shall not constitute notice) to:

One Amgen Center Drive
Thousand Oaks, CA 91320
USA
Attn: [*]

Any such notice shall be deemed given on the date received, except any notice received after 5:00 p.m. (in the time zone of the receiving Party) on a business day or received on a non-business day shall be deemed to have been received on the next business day. A Party may add, delete, or change the Person or address to which notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 14.5.

Section 14.6 Compliance With Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

Section 14.7 Non-Use of Names. EnteraBio shall not use the name, trademark, logo, or physical likeness of Amgen or any of its respective officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Amgen's prior written consent. EnteraBio shall require its Affiliates to comply with the foregoing. Amgen shall not use the name, trademark, logo, or physical likeness of EnteraBio or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without EnteraBio's prior written consent. Amgen shall require its Affiliates and Sublicensees to comply with the foregoing.

Section 14.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate) provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any sale of all or substantially all of the assets of the Party that relate to this Agreement to a Third Party, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise (a “**Sale Transaction**”), provided that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by all obligations of the assigning Party under this Agreement. A copy of such written agreement by such assignee shall be provided to the non-assigning Party within ten (10) calendar days of execution of such written agreement. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any attempted assignment of this Agreement in contravention of this Section 14.8 shall be null and void.

Section 14.9 Sale Transaction or Amgen Acquisition. In the event of (x) a Sale Transaction involving Amgen, or (y) the acquisition by Amgen of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, an “**Amgen Acquiree**”), whether by merger, sale of stock, sale of assets or otherwise (an “**Amgen Acquisition**”), intellectual property rights of the acquiring party in a Sale Transaction, if other than one of the Parties to this Agreement (together with any entities that were affiliates of such Third Party immediately prior to such Sale Transaction, a “**Third Party Acquirer**”), or the Amgen Acquiree, as applicable, shall not be included in the Patent Rights or Know-How licensed hereunder by Amgen to EnteraBio or otherwise subject to this Agreement.

Section 14.10 Sale Transaction or EnteraBio Acquisition. In the event of (x) a Sale Transaction involving EnteraBio, or (y) the acquisition by EnteraBio of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, a “**EnteraBio Acquiree**”), whether by merger, sale of stock, sale of assets or otherwise (a “**EnteraBio Acquisition**”), intellectual property rights of the Third Party Acquirer in a Sale Transaction, or the EnteraBio Acquiree, as applicable, shall not be included in the Patent Rights or Know-How licensed hereunder by EnteraBio to Amgen, or otherwise subject to this Agreement, except that to the extent the EnteraBio Acquiree or Third Party Acquirer owns any Blocking Patents relative to any Product, EnteraBio shall and hereby does grant to Amgen a non-exclusive license, [*] until the expiration of the last to expire of such Blocking Patents, on a country-by-country basis or termination of this Agreement relative to such Product, whichever comes first, provided that at the time of such Sale Transaction or EnteraBio Acquisition, such non-exclusive license rights are available for such grant and have not been exclusively licensed to any Third Party.

Section 14.11 Waivers. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 14.12 Rights upon Change of Control of EnteraBio. [*]

Section 14.13 No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof, except for the provisions of Article 10 (with respect to which the persons to which Article 10 applies shall be Third Party beneficiaries for Article 10 only in accordance with the terms and conditions of Article 10).

Section 14.14 Headings; Exhibits. Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement. All Exhibits are incorporated herein by this reference.

Section 14.15 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. The term "including" as used herein means including, without limiting the generality of any description preceding such term. The word "will" shall be construed to have the same meaning and effect as the word "shall". The words "herein", "hereof" and "hereunder" and words of similar import will be construed to refer to this Agreement in its entirety and not to any particular provision hereof. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. All references to "\$" or "dollars" in this Agreement means "U.S. dollars". All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the State of California. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 14.16 Counterparts Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

AMGEN INC.

By: /s/ Raymond Deshaies

Name: Raymond Deshaies

Title: SVP Global Research

ENTERABIO LTD.

By: /s/ Phillip Schwartz

Name: Phillip Schwartz

Title: CEO

[Signature Page to Research Collaboration and License Agreement]

Exhibit A
Press Release

See attached.



Entera Bio Ltd.

Phillip Schwartz,
Chief Executive Officer
Tel: +972-2- 532-7151
phillip@enterabio.com

INTERNATIONAL INVESTOR RELATIONS

Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

Entera Bio and Amgen Enter Strategic Research Collaboration in Inflammatory Disease and Other Serious Illnesses

- - -

Amgen will have the option to advance up to three large molecule programs using Entera's oral delivery technology

- - -

Entera will be eligible to receive up to \$270 million in clinical and commercial milestone payments

Jerusalem, Israel – December 11 2018 – Entera Bio Ltd. (Nasdaq: ENTX) announced today that it has entered into a research collaboration and license agreement with Amgen in inflammatory disease and other serious illnesses. Entera will use its proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. Amgen also has an option to select up to two additional programs to include in the collaboration.

"We are excited to leverage our proprietary oral drug delivery platform in collaboration with Amgen, a leader in the development of large molecule and biologic treatments in inflammatory disease and numerous other disorders," stated Dr. Phillip Schwartz, chief executive officer of Entera. "This collaboration is an important validation of our platform technology. Importantly, the first program included in this agreement is very different from the Oral PTH (1-34) in Entera's pipeline, highlighting the broad applicability of our technology."

Under the terms of the agreement, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to \$270 million in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs.

Entera will retain all intellectual property rights to its drug delivery technology, which under this collaboration will be licensed to Amgen exclusively for Amgen's nominated drug targets. Amgen will retain all rights to its large molecules and any subsequent improvements.

About Entera Bio Ltd.

Entera Bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical needs. The Company is initially applying its technology to develop an oral formulation of a human parathyroid hormone analog, Oral PTH (1-34), for treatment of hypoparathyroidism and osteoporosis.

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Entera's proprietary platform technology, consists of two components: a small molecule that enhances the absorption of a large molecule therapeutic agents and a second component that "protects" the large molecule from digestion in the gastrointestinal tract. This synergistic system is intended to increase oral bioavailability and decrease the variability associated with the oral administration of large molecule biologics and synthetic protein therapeutic agents.

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Currently, biological entities and other large molecules can only be delivered via injections and or other non-oral pathways. However, oral drug delivery is the easiest method for self-administering medications, offers patients greater dosing flexibility, and has the highest patient acceptance and compliance rates as compared to all other routes of drug administration.

Forward Looking Statements

This press release contains "forward-looking statements." Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in the Company's Registration Statement on Form F-1 and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Contact:

Bob Yedid

LifeSci Advisors, LLC 646-597-6989

bob@lifesciadvisors.com

CERTIFICATIONS

I, Dr. Phillip Schwartz, certify that:

1. I have reviewed this annual report on Form 20-F of Entera Bio Ltd.;
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;
3. [Reserved]
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [Reserved]
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 17, 2019

/s/ Dr. Phillip Schwartz
Name: Dr. Phillip Schwartz
Title: Chief Executive Officer

CERTIFICATIONS

I, Mira Rosenzweig, certify that:

1. I have reviewed this annual report on Form 20-F of Entera Bio Ltd.;
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;
3. [Reserved]
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [Reserved]
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 17, 2019

/s/ Mira Rosenzweig

Name: Mira Rosenzweig

Title: Chief Financial Officer
