

Dealdoc

Licensing agreement for rhAAT

rEVO Biologics LFB Biotechnologies

Mar 31 2014

Licensing agreement for rhAAT

Companies: rEVO Biologics LFB Biotechnologies

Announcement date: Mar 31 2014

Deal value, US\$m: n/d

- Details
- Financials
- Termsheet
- Press Release
- Filing Data
- Contract

Details

Announcement date:
Start date:
Mar 31 2014
Industry sectors:
Biotech
Compound name:
Fxclusivity:
Asset type:
Compound

Therapy areas:

Genetic disorders

Respiratory » Emphysema

Technology types: Biological compounds

Deal components: Licensing
Geographic focus: Worldwide

Financials

Deal value, US\$m: n/d

Royalty rates, %:

1 : percentage of net sales on a product-by-product and

country-by-country basis

Semi-quant royalties: Low single digit

Termsheet

Exclusive license agreement where LFB USA granted us an exclusive, worldwide license (or sub-license with respect to third-party in-licensed intellectual property) to develop and commercialize rhAAT worldwide under any intellectual property owned by or licensed to LFB USA.

We have the right to grant sublicenses outright to third parties.

In consideration for the licenses and other rights granted to us, we are obligated to pay LFB USA a percentage of net sales on a product-by-product and country-by-country basis.

Additionally, we are required to procure all rhAAT required for our clinical and commercial activities exclusively from LFB USA until the seventh anniversary of the FDA approval of rhAAT, if we receive any such approval.

LFB USA supplies us rhAAT at cost plus a markup which percentage is in the low double digit range.

However, if LFB USA subcontracts the downstream manufacturing or fill and finish processes, the markup will be reduced for the costs related to the subcontracted activities.

The royalties on the net sales that may be payable to LFB USA are in the low single digit range.

We are also required to reimburse LFB USA for any royalties due to Tufts based on net sales, whether direct or indirect, of rhAAT in the United States

The royalties for Tufts are under 1% with such indirect amounts capped at a high single digit percentage of the distributor fees.

We are required to use all commercially reasonable efforts to develop licensed products and are subject to specific development milestones.

If we are unable to meet these milestones, the exclusive license agreement will be automatically terminated.

Either party may also unilaterally terminate the license agreement at any time with prior notice or following uncured breach or insolvency.

Absent early termination, the agreement will automatically terminate upon the expiration of all issued patents and filed patent applications within the patent rights covered by the agreement or at the end of the royalty term, whichever is later.

The longest lived patent rights licensed to us under the agreement are currently expected to expire in 2032.

We and LFB USA have each agreed to indemnify the other party for all liabilities and damages arising from third party claims as a result of any breach of covenants or warranties, other than those resulting from the other party's gross negligence or willful misconduct.

The agreement is not assignable without written consent.

Press Release

Not available.

Filing Data

S1 abstract - 2014

On March 31, 2014, we entered into an exclusive license agreement where LFB USA granted us an exclusive, worldwide license (or sub-license with respect to third-party in-licensed intellectual property) to develop and commercialize rhAAT worldwide under any intellectual property owned by or licensed to LFB USA. We have the right to grant sublicenses outright to third parties. In consideration for the licenses and other rights granted to us, we are obligated to pay LFB USA a percentage of net sales on a product-by-product and country-by-country basis. Additionally, we are required to procure all rhAAT required for our clinical and commercial activities exclusively from LFB USA until the seventh anniversary of the FDA approval of rhAAT, if we receive any such approval. LFB USA supplies us rhAAT at cost plus a markup which percentage is in the low double digit range. However, if LFB USA subcontracts the downstream manufacturing or fill and finish processes, the markup will be reduced for the costs related to the subcontracted activities. The royalties on the net sales that may be payable to LFB USA are in the low single digit range. We are also required to reimburse LFB USA for any royalties due to Tufts based on net sales, whether direct or indirect, of rhAAT in the United States. The royalties for Tufts are under 1% with such indirect amounts capped at a high single digit percentage of the distributor fees. We are required to use all commercially reasonable efforts to develop licensed products and are subject to specific development milestones. If we are unable to meet these milestones, the exclusive license agreement will be automatically terminated. Either party may also unilaterally terminate the license agreement at any time with prior notice or following uncured breach or insolvency. Absent early termination, the agreement will automatically terminate upon the expiration of all issued patents and filed patent applications within the patent rights covered by the agreement or at the end of the royalty term, whichever is later. The longest lived patent rights licensed to us under the agreement are currently expected to expire in 2032.

We and LFB USA have each agreed to indemnify the other party for all liabilities and damages arising from third party claims as a result of any breach of covenants or warranties, other than those resulting from the other party's gross negligence or willful misconduct. The agreement is not assignable without written consent.

Contract

EXCLUSIVE LICENSE AGREEMENT

This LICENSE AGREEMENT (the "Agreement"), is made and effective as of March 31, 2014 (the "Effective Date") by rEVO Biologics, Inc., a Massachusetts corporation with a business address at 175 Crossing Boulevard, Framingham, Massachusetts 01702 ("Licensee") and, LFB USA, Inc., a Delaware corporation, having its principal place of business located at 175 Crossing Boulevard, Framingham, Massachusetts 01702 ("LFB USA") each of LFB USA and Licensee being a "Party," and collectively, the "Parties").

BACKGROUND

A. WHEREAS, Licensee and LFB USA desire that LFB USA grant a license to Licensee as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the covenants and premises contained herein, the parties therefore agree as follows:

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ARTICLE 1

DEFINITIONS

As used in this Agreement, the following terms have the meaning set forth in this ARTICLE 1.

- 1.1 "Affiliate" means any corporation or other entity that is directly or indirectly controlling, controlled by or under the common control with a Party hereto. For the purpose of this Agreement, "control" includes the direct or indirect ownership of at least fifty percent (50%) of the outstanding shares or other voting rights of the subject entity to elect directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority. For avoidance of doubt, LFB USA and Licensee shall be deemed not to be Affiliates of one another for the purposes of this Agreement.
- 1.2 "AAT Product" means any pharmaceutical or medicinal item, substance, formulation or dosage that is comprised of, or contains, a AAT Compound (whether or not such AAT Compound is the sole active ingredient).
- 1.3 "AAT Compound" means a recombinant form of human Alpha 1 Antitrypsin obtained from the milk of a transgenic animal.
- 1.4 "AAT Field" All therapeutic, application of the AAT Product in human therapy
- 1.5 "AAT Territory" means the entire world.

- 1.6 "Applicable Laws" means, with respect to each Party, all laws, codes, ordinances, statutes, rules, regulations, orders, decrees, judgments, injunctions, notices or binding agreements promulgated or entered into by any Governmental Authority having jurisdiction over such Party or such Party's obligations under this Agreement, as the same may be amended, modified or repealed from time to time.
- 1.7 "Business Day" means any day other than Saturday, Sunday or any other day on which commercial banks in the City of New York or Paris, France are authorized or required by law to remain closed.
- 1.8 "Code" has the meaning set forth in Section 13.8.
- 1.9 "Combination Product" has the meaning set forth in Section 1.35.
- 1.10 "Commercialization" or "Commercialize" means any and all activities directed to the offering for sale and sale of AAT Product after Marketing Authorization has been obtained with respect to AAT Product, including, (a) activities directed to marketing, promoting, detailing, distributing, Manufacturing, importing, selling and offering to sell such Product; (b) interacting with Regulatory Authorities regarding any of the foregoing; and (c) seeking pricing approvals and reimbursement approvals for AAT Product (d) post approval clinical trials. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.
- 1.11 "Commercially Reasonable Efforts" means with respect to the efforts to be expended by a Party with respect to the objective that is the subject of such efforts, reasonable, good faith efforts and resources to accomplish such objective that such Party would normally use to accomplish a similar objective under similar circumstances, taking into account issues of scientific risk, patent coverage, safety and efficacy, product profile, competitiveness of the marketplace, proprietary position, the regulatory structure involved and potential profitability (including pricing and reimbursement status achieved or likely to be achieved) and other relevant factors, including technical, legal, scientific and/or medical factors.
- 1.12 "Confidential Information" means the terms of this Agreement (but not its existence) and all trade secrets, know-how and other proprietary confidential information of a Party (including technical, business, financial and market information, non-published patent disclosures, non-published patent applications, structures, models, techniques, formula processes, compositions, compounds, antigens, antibodies, hybridomas, apparatus, designs, sketches, photographs, plans, drawings, specifications, samples, reports, customer lists, price lists, studies, findings, inventions and ideas) disclosed by either Party or obtained through observation or examination of the other's information or developments, but only to the extent that such information is maintained as confidential by the Party providing same and provided that Confidential Information shall only include information that is either marked as "CONFIDENTIAL" or that, due to the nature of the information, the receiving Party should reasonably know that it is confidential.
- 1.13 "Control(led)" means, with respect to any material, information or intellectual property right, that a Party owns or has a license to such item or right, and has the ability to grant the other Party access, a license or a sublicense (as applicable) in or to such item or right as provided in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

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- 1.14 "Cover(ed)" means, with respect to any Patent Right and the subject matter at issue, that, but for an ownership right or license granted under a Valid Claim of such Patent Right, the manufacture, development, use, sale, offer for sale, exportation or importation of the subject matter at issue would infringe such Valid Claim or, in the case of a Patent Right that is a patent application, would infringe a Valid Claim in such patent application if it were to issue as a patent.
- 1.15 "Development" or "Develop" means, with respect to AAT Product, (a) all non-clinical and clinical drug development activities that are undertaken after the Effective Date up to and including the date of obtaining of Marketing Authorization of AAT Product to obtain including (i) the conduct of clinical trials, toxicology and pharmacology testing, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, analytical method development, human clinical studies and regulatory affairs activities and statistical analysis and report writing; (ii) the preparation of Clinical Trial design and operations; (iii) preparing and filing drug approval applications, and (b) any and all other activities that may be necessary or useful to obtain Regulatory Approval. When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning.
- 1.16 "Disclosing Party" has the meaning set forth in Section 8.1.
- 1.17 "Disputes" has the meaning set forth in Section 14.1.
- 1.18 "Distributor" means any Person that purchases Product from rEVO or any of rEVO's Affiliates or Sublicensees for purposes of resale of Product to end users in the Territory (including any wholesalers, pharmacists or hospitals).
- 1.19 "Downstream Process Manufacturing Rights" means any and all Patent Right and Know-How that is Controlled by LFB USA on or after the Effective Date that (a) relates to AAT Compound or AAT Product and (b) is necessary or useful to perform purification of starting material obtained from the Upstream Process with one or several steps which may be chromatographic steps, and filtration steps, formulation, aseptic filtration and freezing that are in accordance with agreed process descriptions to manufacture, testing and release formulated bulk drug substance that meets applicable requirements for fill finish of AAT Product.
- 1.20 "Encumbrance" means any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal or security interest of any kind.
- 1.21 "Fill and Finish Manufacturing Rights" means any and all Patent Right and Know-How that is Controlled by LFB USA on or after the Effective Date that (a) relates to AAT Compound or AAT Product and (b) is necessary or useful to perform manufacturing of final drug product in a form available for sale or other patient use including fill, finish and packaging with coding, sealing and stoppering, labelling, primary and secondary packaging, and also all required testing, and release of AAT Product.

- 3 -

- 1.22 "Governmental Authority" means any United States, France, or non-United States or France federal, national, supranational, state, provincial, local, or similar government, governmental, regulatory or administrative authority, agency or commission or any court, tribunal, or judicial or arbitral body.
- 1.23 "Indemnified Parties" has the meaning set forth in Section 12.1.
- 1.24 "Indemnified Proceeding" has the meaning set forth in Section 12.2.
- 1.25 "Indemnifying Party" has the meaning set forth in Section 12.2.
- 1.26 "Invention" means any process, method, composition of matter, article of manufacture, improvement, or finding that is conceived or reduced to practice by LFB USA, and the ownership of which is kept within LFB USA, prior to the Effective Date or during the Term. Any process, method, composition of matter, article of manufacture, improvement, or finding that is described in a filed patent application prior to the Effective Date shall be deemed not to be an Invention for the purposes of this Agreement.
- 1.27 "Know-How" means any and all know-how, trade secrets and proprietary technology, including enhancements, manufacturing processes or protocols, writings, documentation, data, technical information, techniques, results of experimentation and testing, diagnostic and prognostic assays, specifications, databases, any and all laboratory, research, pharmacological, toxicological, analytical, quality control, pre-clinical and clinical data, safety data, chemistry, manufacturing and control data and other information and materials, including all of the foregoing potentially

patentable, even if not patented.

- 1.28 "Knowledge of LFB USA" means the actual (and not imputed) knowledge of any executive officer or member of the board of directors of LFB USA
- 1.29 "LFB USA Fully Burdened Manufacturing Cost" means [***]
- 1.30 "Licensed Patent Rights" means any Patent Rights that are Controlled by LFB USA during the Term and that (a) contain one or more claims that Cover any Product; and (b) are necessary or useful for rEVO to Develop and/or Commercialize AAT Compound or AAT Product in the AAT Field and in the AAT Territory. For purposes of clarity, (a) the Licensed Patent Rights existing as of the Effective Date are listed on Schedule 1.30 attached hereto and (b) Schedule 1.30 shall be updated by LFB USA by written notice to rEVO on an annual basis during the Term to include any additional patents and patent applications not previously listed; provided, that, the exclusion of a patent or patent application from Schedule 1.30 shall not be deemed to be a conclusive indication of whether that patent or application is or should be considered a "Licensed Patent Right" for purposes of this Agreement.
- 1.31 "Licensed Technology" means Licensed Patent Rights and Licensed Know How
- 1.32 "Licensee Financial Records" has the meaning set forth in Section 6.5.1.
- 1.33 "Licensee Indemnified Party" has the meaning set forth in Section 12.1.
- 4 -

- 1.34 "Loss" has the meaning set forth in Section 12.1.
- 1.35 "Net Sales" means [***]
- 1.36 "Manufacture" or "Manufacturing" or "Manufactured" means all activities related to the production of any AAT Product, including the manufacture, receipt, inspection, storage and handling of materials, and the manufacture, processing, purification, packaging, labeling, warehousing, quality control testing (including in-process release and stability testing), shipping and release of AAT Product, including without limitation, the optimization of a commercial-grade Manufacturing process for the Manufacture of AAT Product including, test method development and stability testing, formulation, validation, productivity, trouble shooting and next generation formulation, process development, Manufacturing scale-up, strain improvements, development-stage Manufacturing, and quality assurance/quality control development.
- 1.37 "Patent Rights" means all intellectual property rights represented by or issuing from (a) any United States and foreign issued patents and patent applications, as well as any priority attached priority rights (b) all patent applications filed in any jurisdiction corresponding to or claiming priority from the patents and/or patent applications referred to in the foregoing clauses (a); (c) all divisionals, continuations and continuations-in-part of the patent applications referred to in the foregoing clauses (a) and (b); (d) all patents issuing from the patent applications referred to in the foregoing clauses (a), (b) and (c); (e) all reissues, re-examination certificates, registrations, confirmations, extensions, substitutions, renewals, amendments and supplementary protection certificates of the patent and/or patent applications referred to in the foregoing clauses (a) through (d); and (f) all foreign counterparts of the patents and patent applications referred to in the foregoing clauses (a) through (e).
- 1.38 "Person" means any individual, partnership (whether general or limited), limited liability company, corporation, trust, estate, association, nominee or other entity.
- 1.39 "Product" means a product that is Covered by one or more Valid Claims of the Licensed Technology, and/or incorporates, is manufactured using or is derived from the Licensed Technology.
- 1.40 "Receiving Party" has the meaning set forth in Section 8.1.
- 1.41 "Research Agreement" means any research collaboration agreement, material transfer agreement, research services agreement, sponsored research agreement, or similar agreement by and between LFB USA and a Third Party, prior to or after the Effective Date, under which the parties to such agreement conduct research related to the Licensed Technology.
- 1.42 "Royalty Term" means the period beginning on the date of First Commercial Sale of AAT Product in the Territory and ending ten (10) years from the date of the First Commercial Sale of AAT Product in the Territory.
- 1.43 "Sublicensee" means any Third Party to which rEVO grants a sublicense in accordance with Section 2.2.

1.44 "Tangible Materials" means any tangible documentation, data, reports, records or other information, whether written or electronic, that is Controlled by LFB USA, embodying or related to the Licensed Technology, including, but not limited to, documentation, patent applications and invention disclosures.

- 5 -

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

- 1.45 "Term" has the meaning set forth in Section 13.1.
- 1.46 "Third Party" means any Person other than a Party or an Affiliate of a Party.
- 1.47 "Third Party In-License Agreement" means any license or sublicense agreement entered into between a Third Party licensor and LFB USA pursuant to which LFB USA is granted a license or sublicense to any Patent Rights or Know-How by such Third Party, including the agreements set forth on Schedule 1.47. Schedule 1.47 will be completed, amended or updated from time to time by the Parties. To the extent an agreement listed on Schedule 1.47 is a cross-license agreement, only the terms and conditions of such agreement relating to the in-license aspects of the cross-license shall be deemed to be a Third Party In-License Agreement.
- 1.48 "Upstream Process Manufacturing Rights" means any and all Patent Right and Know-How that is Controlled by LFB USA on or after the Effective Date that (a) relates to Atryn Compound or Atryn Product and (b) is necessary or useful to perform production, testing and release of milk of transgenic goats expressing containing Atryn Compound, and may include milk previously clarified by filtration, treated for viral inactivation, pasteurizated, concentrated, diafiltered by tangential filtration and/or filtered before freezing for storage. For the avoidance of doubt, Upstream Process Manufacturing Rights also includes Patent Right and Know-How that is Controlled by LFB USA required to generate, select, and maintain and adequate animal herd for milk production, including breeding, maintenance and management of the animals and animal facilities
- 1.49 "Valid Claim" means any claim in any (a) unexpired and issued patent that has not been disclaimed, revoked or held invalid by a final nonappealable decision of a court or other governmental agency of competent jurisdiction, or (b) patent application that has not lapsed, in the case of a provisional patent application, or been cancelled, withdrawn or abandoned without the possibility of revival.

ARTICLE 2

LICENSES

2.1 Grant of License to LFB USA. Subject to the terms and conditions of this Agreement, LFB USA hereby grants to rEVO an exclusive (including with respect to LFB USA and their respective Affiliates), worldwide, royalty-bearing license or sublicense (with respect to the Third Party In-License Agreements), including the right to grant sublicenses as provided in Section 2.2, under the Licensed Know-How and Licensed Patent Rights to use, develop, sell or offer for sale AAT Product anywhere in the AAT Territory and in the AAT Field or to export or import AAT Product throughout the AAT Territory.

- 6 -

- 2.2 Right to Sublicense.
- (i) Sublicense. rEVO shall have the right to grant sublicenses under the licenses granted to it under Section 2.1 to any Sublicensee; with LFB USA prior written notification provided, that, (a) the terms of each such sublicense shall be consistent with the rights and obligations of rEVO under the Agreement; (b) it shall be a condition of any such sublicense that such Sublicensee agrees to be bound by the terms of this Agreement applicable to the Development and Commercialization of AAT Product in the Field in the Territory; (c) rEVO shall provide LFB USA with a copy of any such Sublicense Agreement within [***] of the execution of each such Sublicense Agreement; and (d) rEVO shall not be relieved of its obligations pursuant to this Agreement as a result of such sublicense, except to the extent such obligations are satisfactorily performed by any such sublicense.
- (ii) Grant of Rights to Distributors. rEVO or any of its Affiliates and Sublicensees shall have the right, with LFB USA prior written notification, to appoint one or more Distributors for AAT Product in the Territory. rEVO shall provide LFB USA with a copy of each such agreement with any Distributor within [***] of execution of such agreement.

- 2.3 Grantback License. Licensee hereby grants to LFB USA a royalty-free, non-exclusive license, with the full right to sublicense through multiple tiers, under any Know-How or Patent Rights that are improvements to the LFB USA Technology or Third Party Technology, that are Controlled by Licensee during the Term of this Agreement, and that are necessary or useful to make, have made, use, develop, sell, offer for sale, export and import products throughout the world, other than AAT Product.
- 2.4 No Implied Rights. Only the licenses granted pursuant to the express terms of this Agreement are of any legal force or effect. No other license rights are granted or created by implication, estoppel or otherwise. All rights not explicitly granted hereunder are reserved.
- 2.5 Retained Rights. Notwithstanding Section 2.1 above, the Parties acknowledge and agree that, as between the Parties, LFB USA retains ownership and/or Control of all the Licensed Know-How and Licensed Patent Rights, including the Third Party In-License Agreements, Delivery/Transfer.

ARTICLE 3 - DELIVERY/TRANSFER

- 3.1 Tangible Materials. Upon request of licensee, LFB USA shall, at Licensee's sole cost and expense, deliver to Licensee reasonable quantities, samples or copies of any requested, existing Tangible Materials in possession of LFB USA that are necessary or useful for Licensee to exercise the rights licensed to it hereunder.
- 3.2 Research Agreements. LFB USA agrees to use Commercially Reasonable Efforts to assert any contractual rights it has to Control any Patent Rights and Know-How arising from any Research Agreement prior to or after the Effective Date and to include such Patent Rights and Know-How in the Licensed Technology. As between LFB USA and Licensee, LFB USA shall remain responsible for all obligations under each Research Agreement, except to the extent such Research Agreement is or becomes a Third Party In-License Agreement in respect of which Licensee has assumed obligations hereunder.

- 7 -

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ARTICLE 4 - COMMERCIALIZATION MANUFACTURE AND SUPPLY.

- 4.1 Supply Rights. From the Effective Date until seven (7) years from the obtaining by rEVO of a Marketing Authorization for the AAT Product (the "Exclusivity Period"), LFB USA shall be solely responsible for, directly or indirectly, all Manufacturing activities of the Product and related supplies of clinical and commercial batches to support the clinical trial and the sale of the Product in the AAT Territory.
- 4.2 Supply Agreement. Within [***] from the execution of this Agreement, LFB USA and rEVO shall enter into a supply agreement (the "Supply Agreement") which shall be attached in Exhibit B as soon as it is executed by the Parties and which shall include such customary terms of such agreements and shall include the payment by rEVO to LFB USA at a Transfer Price for Product equal to LFB USA's Fully Burdened Manufacturing Costs + [***]. Notwithstanding the foregoing, a markup of only [***] shall be applied on costs related to Downstream process Activities and Fill and Finish Activities, as long as such activities are entirely subcontracted by NEWCO to a Third Party.
- 4.3 Discussion on Manufacturing of Product in the Territory. LFB USA grants rEVO with an option to obtain a worldwide license under Downstream Process Manufacturing Rights and Fill and Finish Manufacturing Rights necessary to manufacture or have manufacture AAT Product. The option will be exercisable as follows: (i) in case of material breach of the Supply Agreement by LFB USA (in such case the license will be free of charge), or (ii) two years before the end of the Exclusivity Period of the supply agreement against financial condition to be negotiated in good faith at the time of the exercise.

ARTICLE 5

CONSIDERATION

- 5.1 Royalty Payments. In consideration for the licenses and other rights granted to Licensee hereunder, rEVO shall pay LFB USA a non-refundable, non-creditable royalty commencing with the First Commercial Sale of AAT Product in any country in the Territory and ending upon the last day of the last Royalty Term for such Product in such country. The royalty rate shall be equal to [***]
- 5.2 Third Party In-Licenses. Subject to the provisions of ARTICLE 6 hereof, Licensee shall be responsible for the payment of royalties and other payment obligations, if any, due to any Third Parties relating to Licensed Technology that have been licensed to LFB USA and are sublicensed to Licensee hereunder, including any payments of Third Party Royalties due under any Third Party In-License Agreement. Unless and until the time Licensee makes arrangements to make direct payments to the appropriate Third Party due any payment under this Section 5.1, LFB USA shall remain responsible for making such payment when due to such Third Party, and Licensee shall reimburse LFB USA for such payment in accordance with Section 6.2 upon receipt of an appropriate invoice from LFB USA.

- 8 -

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ARTICLE 6

PAYMENTS

- 6.1 Timing and Method of Payment. Commencing with the first commercial sale of Products hereunder, on or before [***] following the end of each calendar month, Licensee shall provide to LFB USA written accounts of the Net Sales of AAT Products subject to royalty hereunder made during the prior calendar month and prior calendar quarter, as the case may be, and at the end of each calendar quarter shall pay to LFB USA the royalties due (as calculated above) on such Net Sales of AAT Products within [***]. Except as otherwise provided in this Agreement, LFB USA shall provide Licensee with an invoice for any other payments due under this Agreement and Licensee shall make all payments that are due within [***] after receipt of such invoice.
- 6.2 Third Party In License Payments. Licensee shall make all payments that are due under any Third Party In-License Agreement in a manner consistent with the timeframes and method of payment set forth in such Third Party In-License Agreement, as the case may be. Licensee may, at its sole option, either make such payment directly to such Third Party (if permitted by such Third Party and upon receipt of an invoice from such Third Party), or make such payment to LFB USA for the benefit of such Third Party. In the latter case, LFB USA shall provide Licensee with an invoice for such payments as they become due and Licensee shall make all payments in accordance with the terms of such invoice, but in no event later than [***] after receipt of such invoice.
- 6.3 Mode of Payment; Currency Conversion. As used in this Agreement, all references to "U.S. dollars," "US\$," "dollars" and "\$" are to the legal currency of the United States, and Licensee shall make all payments required under this by wire transfer in immediately available funds to an account designated by LFB USA, in U.S. dollars.
- 6.4 Taxes. LFB USA shall bear any and all taxes levied on account of any payment received by LFB USA under this Agreement. In the event that Licensee is required, under Applicable Laws, to withhold any deduction or tax from any payment due to LFB USA under this Agreement, such amount shall be deducted from the payment to be made by Licensee and paid to the proper taxing authority; provided, however, that Licensee shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify LFB USA so that LFB USA may take lawful actions to avoid and minimize such withholding. Licensee shall promptly furnish LFB USA with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the relevant Governmental Authority related to any application by LFB USA for foreign tax credit for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.
- 6.5 Record Keeping and Royalty Review.
- (i) Licensee's Record Keeping Obligation. Commencing with the first commercial sale of Products hereunder, Licensee shall keep and maintain financial statements and records relating exclusively to the subject matter of this Agreement, solely for the purposes of confirming the Net Sales of AAT Products to be reported (the "Licensee Financial Records").

- 9 -

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- (ii) LFB USA's Right to Audit. LFB USA, through an independent certified public accountant reasonably acceptable to Licensee, subject to a written non-disclosure agreement with Licensee, may, during normal business hours and upon five (5) days' advance written notice to Licensee, and no more often than once per calendar year, inspect the Licensee Financial Records. Licensee may have a representative present at all such inspections and shall be provided with a copy of the report produced by such auditor. Such audits shall be carried out in a manner calculated not to unreasonably interfere with Licensee's conduct of business. Such certified public accountant shall comply with all of Licensee's safety and security requirements during any visits to Licensee's facilities. LFB USA's right to inspect the Licensee Financial Records is limited to the current year for which Net Sales of Products are to be reported and payable and the immediately preceding three (3) fiscal year periods.
- (iii) Cost of Audit; Underpayment. The cost of any audit under Section 6.5.2 shall be borne by LFB USA, unless such audit reveals a deficiency of [***] or more in the Net Sales of Products reported by Licensee for the period being inspected. If the audit reveals a deficiency of [***] or more in the Net Sales of Products reported by Licensee for the period being inspected, Licensee shall pay the reasonable costs of such audit and shall promptly, and in no event later than [***] from the date it receives the auditor's report, pay the amount of the underpayment. If royalties are understated by less than [***], Licensee shall include such understated amount with the next scheduled payment pursuant to Section .

ARTICLE 7

DUE DILIGENCE

- 7.1 Foreign Registration. Licensee agrees to register this Agreement with any foreign Governmental Authority which requires such registration, and Licensee shall pay all costs and legal fees in connection therewith.
- 7.2 Diligence. Subject to the diligence requirements of any Third Party In-License Agreement, Licensee shall use Commercially Reasonable Efforts to develop and/or commercialize Products during the Term. In addition to the foregoing, Licensee shall use Commercially Reasonable Efforts to achieve the following obligations (the "Development Milestones"):

• [***]

In the case where the Licensee is unable to provide (i) [***] evidences of the achievement of Development Milestone [***], the Agreement shall be automatically terminated as set forth ARTICLE 13 below.

7.3 Records; Reports. rEVO and/or its Affiliates, Sublicensees, Distributors shall (a) maintain records of its activities under the Development program in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work performed and results achieved in the performance of the Development activities and (b) keep LFB USA regularly informed of the progress of its efforts to Develop

- 10 -

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Products in the Territory, including without limitation, providing LFB USA with an annual development report (each, a "Development Report") (to be delivered with each annual update to the Development Plan) that summarizes: (a) significant Development activities conducted during the preceding Calendar Year and results obtained with respect to Compounds and Products (including the status of all Clinical Trials), (b) Significant Development Events applicable to the Compounds and/or Products, (c) a summary of all Program Technology conceived or reduced to practice by rEVO over such period, (d) a non-binding estimate of the expected timing of any milestone events with respect to Products and (e) such other information that rEVO has in its possession as may be reasonably requested from time to time by LFB USA. The Development Report shall be deemed rEVO Confidential Information.

ARTICLE 8

CONFIDENTIAL INFORMATION

- 8.1 Confidentiality, Permitted Use and Disclosure. LFB USA and Licensee (each, a "Receiving Party") shall each hold in confidence any Confidential Information transferred, disclosed, or made available to it under this Agreement by the other Party (the "Disclosing Party") and shall protect the confidentiality thereof with the same degree of care that the Receiving Party exercises with respect to its own information of a like nature, but in no event less than reasonable care. Without the prior written consent of the Disclosing Party, the Receiving Party shall not use, disclose, or distribute the Disclosing Party's Confidential Information, in whole or in part, except as required by the Receiving Party to perform its obligations under this Agreement or in furtherance of its rights under this Agreement. Access to the Disclosing Party's Confidential Information shall be restricted to the Receiving Party, its Affiliates and sublicensees, and their respective employees, agents and consultants, who, in each case, need to have access to carry out a permitted use and are bound in writing to non-use and confidentiality obligations no less stringent than the obligations set forth in this Section 8.1. The obligations set forth in this Section 8.1 shall survive any termination or expiration of this Agreement.
- 8.2 Exceptions. The Recipient's confidentiality and non-use obligations shall not apply to any Confidential Information of the Disclosing Party which, to the extent the Recipient has documentary evidence to that effect:
- (i) was already known to the Recipient at the time of disclosure by the Disclosing Party;
- (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure by the Disclosing Party;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure other than through any act or omission of the Recipient;
- (iv) was subsequently lawfully disclosed to the Recipient by a Third Party who had no obligation of confidentiality, directly or indirectly, to the Disclosing Party or an Affiliate of the Disclosing Party; or

- 11 -

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- (v) is required to be disclosed by the Recipient by law or under a court order, provided, however, that the Recipient shall give the Disclosing Party sufficient advance notice to permit it to seek a protective order or similar order with respect to such information and thereafter discloses only the minimum information required to be disclosed in order to comply, whether or not a protective order or other similar order is sought or obtained by the Disclosing Party.
- 8.3 Use of Name; Disclosure of Terms of the Agreement. Except as may be required by Applicable Law or regulation, neither Party shall disclose any terms or conditions of this Agreement without the prior written consent of the other Party, provided that either Party may disclose such terms and conditions to any Third Party with whom such Party has entered into or proposes to enter into a business relationship that would result in a permitted license, sublicense or assignment in accordance with the terms and conditions of this Agreement, provided any such Third Party is informed of the confidentiality and use restrictions in this Agreement with respect to such terms and conditions and agrees to abide by such restrictions.
- 8.4 Effect of Expiration or Termination. The Receiving Party shall, upon expiration or termination of this Agreement, immediately discontinue use of the Disclosing Party's Confidential Information (except to the extent that such Party or any of its Affiliates or sublicensees retains a right or license to use or has purchased such Confidential Information). Within [***] after expiration or termination of this Agreement, all materials containing the Disclosing Party's Confidential Information shall be, as directed by the Disclosing Party, returned by the Receiving Party or destroyed, provided, however, that the Receiving Party may retain copies of Confidential Information which such Party or any of its Affiliates or sublicensees retains a right or license to use or has purchased, and the Receiving Party shall be entitled to retain a file copy of the Confidential Information under the control of its General Counsel or its outside counsel for archival purposes and for monitoring its obligations under this Agreement.
- 8.5 Authorized Disclosures. In addition to disclosures otherwise allowed under this ARTICLE 8, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is necessary in the following instances: (i) filing or prosecuting Patent Rights as permitted by this Agreement; (ii) prosecuting or defending litigation as permitted by this Agreement; (iii) complying with applicable court orders or governmental regulations; and (iv) disclosure to consultants, investors, bankers, lawyers, accountants, agents or other Third Parties in connection with due diligence or similar investigations by such Third Parties, provided, in each case, that any such consultant, investor, banker, lawyer, accountant, agent or Third Party is bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement. Subject to Licensee's consent, which consent shall not be unreasonably withheld or delayed, LFB USA may also disclose Confidential Information belonging to Licensee to the extent such disclosure is necessary under the provisions of the Technology Transfer Agreement.

ARTICLE 9

REPRESENTATIONS AND WARRANTIES

- 9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that:
- (i) it has the power and authority to execute and deliver this Agreement and to perform the acts required of it hereunder;
- 12 -

- (ii) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action, and this Agreement constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms; and
- (iii) the execution, delivery and performance of this Agreement does not and will not, as of the Effective Date, (i) violate, conflict with or result in the breach of any provision of its certificate of incorporation, operating agreement or by laws, (ii) violate any Applicable Law, or (iii) result in any breach of, constitute a default (or event which with the giving of notice or lapse of time, or both, would become a default) under, or require any consent under any contract, agreement or arrangement by which it is bound.
- $9.2\,LFB\,USA\,Representations\,and\,Warranties.\,LFB\,USA\,represents\,and\,warrants\,to\,Licensee\,that,\,as\,of\,the\,Effective\,Date:$
- (i) it Controls the Licensed Technology to the extent necessary to grant the licenses to Licensee under Section 2.1, hereof;
- (ii) it has not notified any Third Party in writing that such Third Party is engaging in conduct that infringes upon, conflicts with, or misappropriates or otherwise violates LFB USA's rights in the Licensed Technology;

- (iii) it has not received any written notice from any Third Party that the practice of any Licensed Technology infringes upon, conflicts with, or misappropriates or otherwise violates the proprietary intellectual property rights of any Third Party;
- (iv) to the Knowledge of LFB USA none of the Licensed Technology has been adjudged invalid or unenforceable by any court of competent iurisdiction:
- (v) to the Knowledge of LFB USA, LFB USA has the right to grant to Licensee the licenses and sublicenses under the Licensed Technology that it purports to grant hereunder;
- (vi) it is not, and will not be as a result of the execution, delivery or performance of this Agreement or the grant of the licenses and sublicenses contemplated hereby, in breach, or violation of, or default under, any Third Party In-License Agreement, modification or acceleration under any such Agreement.
- 9.3 No Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN SECTIONS 9.1 AND 9.2, LFB USA MAKES NO WARRANTIES OR REPRESENTATIONS OF ANY KIND, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUE OR OTHERWISE WITH RESPECT TO THE LICENSED TECHNOLOGY, AND TANGIBLE MATERIALS. LFB USA EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

- 13 -

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ARTICLE 10

INTELLECTUAL PROPERTY OWNERSHIP AND PROSECUTION

- 10.1 Ownership of Licensed Technology. The Parties acknowledge and agree that, as between LFB USA and Licensee, LFB USA or its licensors are the owner of all right, title and interest in and to the Licensed Technology.
- 10.2 Prosecution and Maintenance of Licensed Patents. Subject to any Third Party rights under any Third Party In-License Agreement, any Research Agreement, and the Technology Transfer Agreement:
- (i) Prosecution and Maintenance. Licensee shall control the prosecution, and maintenance of all Patent Rights within the Licensed Technology and shall have final decision-making authority (upon consultation with LFB USA) with respect to the preparation, filing, prosecution and maintenance of all such Patent Rights, including any such Patent Rights arising from Inventions, All patent applications under such Patent Rights shall be prepared, prosecuted, filed and maintained by the Licensee or by a patent counsel chosen by Licensee and reasonably acceptable to LFB USA. Said independent patent counsel shall be ultimately responsible to Licensee. Licensee shall keep LFB USA informed of the progress of all patent applications and patents, and to give LFB USA reasonable opportunity to comment on the type and scope of useful claims and the nature of supporting disclosures. Without limiting the foregoing, LFB USA shall cooperate with Licensee to coordinate the preparation, filing, prosecution, and maintenance of such Licensed Patents and LFB USA, and its employees, shall sign any necessary documents or powers needed to carry out such patent preparation, filing, prosecution, defense and maintenance. Funding. All costs and expenses (including attorneys fees) incurred in connection with the preparation, filing, prosecution and maintenance of Patent Rights within the Licensed Technology accruing after the Effective Date shall be borne solely by Licensee. LFB USA shall promptly forward to Licensee any Third Party invoices received by LFB USA with respect to such costs and expenses accruing after the Effective Date, and Licensee shall make all payments that are due under such invoices directly to such Third Party within the time period set forth on such invoice, but in no event more than 30 days after receipt of such invoice.

ARTICLE 11

ENFORCEMENT

11.1 Notification. Each Party agrees to immediately notify the other Party in writing upon becoming aware of any infringement, misappropriation, illegal use or misuse of the Licensed Technology and provide to the other Party all reasonably-available evidence of such infringement.

- 14 -

- 11.2 Enforcement. Subject to any Third Party rights under any Third Party In-License Agreement, any Third Party Out-License Agreement, any Research Agreement, the Technology Transfer Agreement and Section 11.3 below:
- (i) Licensee Right to Enforce. Licensee shall have the sole right (but upon notice to and consultation with LFB USA), but not the obligation, to take action against others in the courts, administrative agencies or otherwise, at Licensee's cost and expense, to prevent or terminate infringement, misappropriation, illegal use or misuse of the Patent Rights within the Licensed Technology, or of any other Licensed Technology. LFB USA shall cooperate with and reasonably assist Licensee in any such action if so requested by Licensee, and, upon Licensee's request, execute, file and deliver all documents and proof necessary for such purpose, including being named as a party to such litigation if requested by Licensee or if required by law. LFB USA shall otherwise have the right to participate and be represented by its own counsel at its own expense in any such action, suit or proceeding. Licensee shall not enter into any settlement or compromise of such action, suit or proceeding that affects or concerns the validity, enforceability, or ownership of any Patent Rights within the Licensed Technology or other Licensed Technology without the prior written information of LFB USA.
- (ii) Declaratory Judgment Actions: Licensed Technology. In the event that a declaratory judgment action alleging invalidity, unenforceability, or non-infringement of the Patent Rights within the Licensed Technology or of any other Licensed Technology is brought against either LFB USA or Licensee, except for the Retained Rights, Licensee shall have the sole right to defend such action at its own expense. In the event that LFB USA is a named party in such action LFB USA agrees that Licensee shall control the defense of such action (including the terms and conditions of any settlement thereof) and all strategic decisions related to any such action shall be made by Licensee; provided, however, that LFB USA shall have the right to passively participate and be represented by its own counsel at its own expense in any such action. LFB USA shall cooperate with and reasonably assist Licensee in any such action if so requested by Licensee, and, upon Licensee's request, execute, file and deliver all documents and proof necessary for such purpose, including being named as a party to such action if requested by Licensee or if required by law. In the event that LFB USA is a named defendant in such declaratory judgment action and Licensee desists or fails (within 60 days after notification) to defend such action, LFB USA shall have the right to defend such action (including the terms and conditions of any settlement thereof) and all strategic decisions related to any such action shall be made by LFB USA; provided, however, that Licensee shall have the right to passively participate and be represented by its own counsel at its own expense in any such action. Licensee shall cooperate with and reasonably assist LFB USA in any such action if so requested by LFB USA, and, upon LFB USA's request, execute, file and deliver all documents and proof necessary for such purpose.

- 15 -

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- (iii) Recoveries. All damages or other compensation of any kind recovered in such action, suit, or proceeding or from any settlement or compromise brought under this ARTICLE 11 shall first be used to reimburse each Party for its expenses in connection with such action, suit or proceeding, (in proportion to the expenses of each Party if recovery is insufficient to cover all such expenses) and the remainder of such recovery shall be allocated one hundred percent (100%) to the Party hereto taking the lead in the action, suit or proceeding.
- 11.3 Limitation Regarding Retained Patent Rights. For avoidance of doubt, LFB USA shall retain all rights to control the enforcement of all Retained Patent Rights for use solely in connection with AAT Product in the AAT Territory, and shall have final decision-making authority with respect to such enforcement and the term "Patent Rights" as used in this ARTICLE 10 shall not include any patent applications or patents within the Retained Patent Rights.

ARTICLE 12

INDEMNIFICATION AND LIMITATION OF LIABILITY

- 12.1 Indemnity. To the greatest extent permitted by Applicable Law, Licensee shall indemnify and hold harmless LFB USA, its Affiliates, and each of their respective officers, directors, employees, agents, members, managers, successors and assigns (each, a "LFB USA Indemnified Party") and LFB USA shall indemnify and hold harmless Licensee, its Affiliates and each of their respective officers, directors, employees, agents, members, successors and assigns (each, a "Licensee Indemnified Party" and collectively, together with the LFB USA Indemnified Party, the "Indemnified Parties"), from and against any and all claims, losses, diminution in value, costs, interest, awards, judgments, penalties, fees (including reasonable fees for attorneys and other professionals), court costs, liabilities, damages and expenses incurred by any LFB USA Indemnified Party or Licensee Indemnified Party (irrespective of whether any such LFB USA Indemnified Party or Licensee Indemnified Party, as applicable, is a party to the action for which indemnification hereunder is sought), (collectively, a "Loss") as a result of, arising out of, or relating to any and all Third Party suits, claims, actions, proceedings, investigations, litigation or demands based upon:
- (i) in the case of Licensee being the Indemnifying Party, (A) any breach of any representation or warranty made by Licensee herein or in any certificate, instrument or document delivered hereunder, (B) any breach of any covenant, agreement or obligation of Licensee contained herein, or in any certificate, instrument or document delivered hereunder, or (C) any act of gross negligence or willful misconduct by Licensee in performing its obligations under this Agreement, or (D) the exercise by Licensee, its Affiliates or sublicensees (other than LFB USA pursuant to a

separate sublicense) of the rights granted hereunder and the use or practice by Licensee, its Affiliates or sublicensee (other than LFB USA pursuant to a separate sublicense) of the Licensed Technology after the Effective Date; in each case, except (1) with respect to Losses for which Licensee is entitled to indemnification under this ARTICLE 12 or (2) to the extent such Loss arises from the gross negligence or willful misconduct of a LFB USA Indemnified Party, and

- 16 -

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(ii) in the case of LFB USA being the Indemnifying Party, (A) any breach of any representation or warranty made by LFB USA herein or in any certificate, instrument or document delivered hereunder, (B) any breach of any covenant, agreement or obligation of LFB USA contained herein, or in any certificate, instrument or document delivered hereunder, (C) any act of gross negligence or willful misconduct by LFB USA in performing its obligations under this Agreement, (D) the use, practice, licensing or sublicensing by LFB USA of the Licensed Technology prior to the Effective Date, (E) any Third Party In-License Agreement, except to the extent such Losses arise from actions or omissions by Licensee under this Agreement, (F) any Research Agreement, and (G) any litigation, claim or action arising from any event or circumstance disclosed by LFB USA to Licensee as an exception to Section 9.2.7; in each case, except (1) with respect to Losses for which LFB USA is entitled to indemnification under this ARTICLE 12 or (2) to the extent such Loss arises from the gross negligence or willful misconduct of a Licensee Indemnified Party.

To the extent that the foregoing undertakings by Licensee and/or LFB USA may be unenforceable for any reason, such Party shall make the maximum contribution to the payment and satisfaction of any Loss that is permissible under Applicable Law.

- 12.2 Notice of Claims. Any Indemnified Party that proposes to assert a right to be indemnified under this ARTICLE 12 shall notify Licensee or LFB USA, as applicable (the "Indemnifying Party"), promptly after receipt of notice of commencement of any action, suit or proceeding against such Indemnified Party (an "Indemnified Proceeding") in respect of which a claim is to be made under this ARTICLE 12, or the incurrence or realization of any Loss in respect of which a claim is to be made under this ARTICLE 12, of the commencement of such Indemnified Proceeding or of such incurrence or realization, enclosing a copy of all relevant documents, including all papers served and claims made, but the omission to so notify the applicable Indemnifying Party promptly of any such Indemnified Proceeding or incurrence or realization shall not relieve (a) such Indemnifying Party from any liability that it may have to such Indemnified Party under this ARTICLE 12 or otherwise, except, as to such Indemnifying Party's liability under this ARTICLE 12, to the extent, but only to the extent, that such Indemnifying Party shall have been prejudiced by such omission, or (b) any other indemnitor from liability that it may have to any Indemnified Party.
- 12.3 Defense of Proceedings. In case any Indemnified Proceeding shall be brought against any Indemnified Party, it shall notify the applicable Indemnifying Party of the commencement thereof and such Indemnifying Party shall be entitled to participate in, and provided such Indemnified Proceeding involves a claim solely for money damages and does not seek an injunction or other equitable relief against the Indemnified Party and is not a criminal or regulatory action, to assume the defense of, such Indemnified Proceeding with counsel reasonably satisfactory to such Indemnified Party, and after notice from such Indemnifying Party to such Indemnified Party of such Indemnifying Party's election to so assume the defense thereof and choice of counsel, and the failure by such Indemnified Party to object to such counsel within 10 Business Days following its receipt of such notice, such Indemnifying Party

- 17 -

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shall not be liable to such Indemnified Party for legal or other expenses related to such Indemnified Proceedings incurred after such notice of election to assume such defense except as provided below and except for the reasonable costs of investigating, monitoring or cooperating in such defense subsequently incurred by such Indemnified Party reasonably necessary in connection with the defense thereof. Such Indemnified Party shall have the right to employ its counsel in any such Indemnified Proceeding, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party unless:

- (i) the employment of counsel by such Indemnified Party at the expense of the applicable Indemnifying Party has been authorized in writing by such Indemnifying Party;
- (ii) such Indemnified Party shall have reasonably concluded in its good faith (which conclusion shall be determinative unless a court determines that such conclusion was not reached reasonably and in good faith) that there is or may be a conflict of interest between the applicable Indemnifying Party and such Indemnified Party in the conduct of the defense of such Indemnified Proceeding or that there are or may be one or more different or additional defenses, claims, counterclaims, or causes of action available to such Indemnified Party (it being agreed that in any case referred to in this clause (b) such Indemnifying Party shall not have the right to direct the defense of such Indemnified Proceeding on behalf of the Indemnified Party);

- (iii) the applicable Indemnifying Party shall not have employed counsel reasonably acceptable to the Indemnified Party, to assume the defense of such Indemnified Proceeding within a reasonable time after notice of the commencement thereof (provided, however, that this clause shall not be deemed to constitute a waiver of any conflict of interest that may arise with respect to any such counsel); or
- (iv) any counsel employed by the applicable Indemnifying Party shall fail to timely commence or diligently conduct the defense of such Indemnified Proceeding:

in each of which cases the fees and expenses of counsel for such Indemnified Party shall be at the expense of such Indemnifying Party. Only one counsel shall be retained by all Indemnified Parties with respect to any Indemnified Proceeding, unless counsel for any Indemnified Party reasonably concludes in good faith (which conclusion shall be determinative unless a court determines that such conclusion was not reached reasonably and in good faith) that there is or may be a conflict of interest between such Indemnified Party and one or more other Indemnified Parties in the conduct of the defense of such Indemnified Proceeding or that there are or may be one or more different or additional defenses, claims, counterclaims, or causes or action available to such Indemnified Party.

12.4 Settlement. Without the prior written consent of an Indemnified Party, such Indemnifying Party shall not settle or compromise, or consent to the entry of any judgment in, any pending or threatened Indemnified Proceeding, unless such settlement, compromise, consent or related judgment (i) includes an unconditional release of such Indemnified Party from all liability for Losses arising out of such claim, action, investigation, suit or other legal

- 18 -

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proceeding, (ii) provides for the payment of money damages as the sole relief for the claimant (whether at law or in equity), (iii) involves no finding or admission of any violation of law or the rights of any Person by the Indemnified Party, and (iv) is not in the nature of a criminal or regulatory action. No Indemnified Party shall settle or compromise, or consent to the entry of any judgment in, any pending or threatened Indemnified Proceeding in respect of which any payment would result hereunder without the prior written consent of the Indemnifying Party, such consent not to be unreasonably conditioned, withheld or delayed.

12.5 Limitation of Liability. EXCEPT WITH RESPECT TO EITHER PARTY'S INDEMNIFICATION OBLIGATIONS PURSUANT TO SECTION 12.1, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY NOR ANY OF THEIR RESPECTIVE DIRECTORS, OFFICERS, MEMBERS, MANAGERS, EMPLOYEES, INDEPENDENT CONTRACTORS OR AGENTS SHALL HAVE ANY LIABILITY OF ANY TYPE (INCLUDING, BUT NOT LIMITED TO, CLAIMS IN CONTRACT, NEGLIGENCE AND TORT LIABILITY) FOR ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, THE LOSS OF OPPORTUNITY, LOSS OF USE OR LOSS OF REVENUE OR PROFIT IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT OR THE SERVICES PERFORMED HEREUNDER, EVEN IF SUCH DAMAGES MAY HAVE BEEN FORESEEABLE.

12.6 Assumption of Obligations Under Other Agreements. LFB USA hereby acknowledges that it is LFB USA's intent that Licensee benefit from all rights licensed to LFB USA (as licensee) under any Third Party In-License Agreement applicable to the LFB USA Technology, and under the Technology Transfer Agreement applicable to the Genzyme Transferred Technology, and LFB USA agrees to cooperate with Licensee to the extent necessary to implement the foregoing. Licensee hereby acknowledges that it is Licensee's intent to assume, and Licensee does hereby assume, all of LFB USA's obligations related to the rights licensed to LFB USA (as licensee) under any Third Party In-License Agreement applicable to the LFB USA Technology, and under the Technology Transfer Agreement applicable to the Genzyme Transferred Technology, and Licensee agrees to cooperate with LFB USA to the extent necessary to implement the foregoing.

ARTICLE 13

TERM AND TERMINATION

- 13.1 Term. The term of this Agreement will commence on the Effective Date, and unless earlier terminated in accordance with this ARTICLE 13, shall expire upon the latest date between i) the expiration or invalidation of the last Valid Claim Covering any Patent Rights within the Licensed Technology or ii) the end of the Royalty Term.
- 13.2 Effect of Expiration. Upon the expiration of this Agreement, the licenses granted to Licensee pursuant to Section 2.1 shall become perpetual, irrevocable, royalty-free, and fully paid-up. Expiration of this Agreement does not release any Party hereto from any liability which, at the time of such expiration, has already accrued to the other Party or which is attributable to a period prior to such expiration, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement prior to expiration.

- 19 -

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- 13.3 Permissive Termination. Licensee may terminate this Agreement, in whole or in part, at any time by providing LFB USA notice in writing at least [***] prior to the effective date of such termination.
- 13.4 Termination for non-achievement of Development Milestones. In case of non-achievement by rEVO of one of the development milestones described in ARTICLE 7, the Agreement shall be immediately and automatically terminated with no indemnification or capacity for rEVO to claim for any damages. Consequently, (i) any and all license granted to rEVO by LFB USA in respect of AAT Product shall automatically revert to LFB USA (including licenses granted according to Section 2.1), (ii) rEVO commits to grant to LFB USA an exclusive, royalties free license or sublicense (with respect to Rights licensed by Third Parties to rEVO), including the right to grant sublicenses, under the all Patent Rights or Invention Controlled by rEVO necessary or useful for LFB USA to Develop such Compounds or Product and/or use, have used, Manufacture, have Manufactured, supply, sell, offer to sell, import, have imported, market, and otherwise Commercialize AAT Product in the AAT Field and in the AAT Territory and iii) rEVO commits to return to LFB USA any and all documentation and material pertaining to AAT Product.
- 13.5 Termination for Cause. Either Party may terminate this Agreement if the other Party has materially breached or defaulted in the performance of any of its obligations hereunder, and such default has continued for [***] after written notice thereof was provided to the breaching Party by the nonbreaching Party. Any termination shall become effective at the end of such [***] period unless the breaching Party has cured or remedied any such breach or default prior to the expiration of such period.
- 13.6 Termination for Insolvency. If voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, are not dismissed within [***] after the date of filing, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within [***] thereafter, the other Party may immediately terminate this Agreement effective upon notice of such termination
- 13.7 Effect of Termination.
- (i) Accrued Rights and Obligations. Termination of this Agreement for any reason does not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the nonbreaching Party may be entitled to seek injunctive relief as a remedy for any such breach. Such remedy shall not be considered to be the exclusive remedy for any such breach of this Agreement, but shall be in addition to all other remedies available at law or in equity.
- 20 -

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- (ii) Licenses. All licenses and sublicenses granted to Licensee hereunder shall terminate upon the termination (but not expiration) in full of this Agreement.
- (iii) Sublicenses. Upon the termination of this Agreement, (i) any and all sublicenses granted by Licensee pursuant to this Agreement shall remain in effect according to its terms with LFB USA deemed for all purposes to be the licensee thereunder; (ii) LFB USA shall be entitled to all payments due from Licensee and LFB USA from any and all sublicensees under such sublicenses in accordance with the terms of such sublicenses; and (iii) such sublicenses shall be deemed assigned to LFB USA if necessary to ensure continued payments.
- (iv) Payment; Return of Confidential Information. Upon the termination of this Agreement, Licensee shall promptly: (A) pay to LFB USA all outstanding amounts, if any, accrued pursuant to this Agreement prior to termination; and (B) at its own expense, return to LFB USA all relevant Confidential Information pursuant to Section 8.4.
- (v) Reversion of Rights. Upon the termination of this Agreement, all rights licensed or otherwise transferred to Licensee hereunder shall revert to LFB USA, and Licensee agrees to execute all instruments necessary and desirable to revest said rights in LFB USA.
- 13.8 Bankruptcy. All rights and licenses granted under this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses to "Intellectual Property" as defined in the Code. The Parties agree that each Party shall retain and may fully exercise all of its rights and elections under the Code.

ARTICLE 14

DISPUTE RESOLUTION

- 14.1 Exclusive Dispute Resolution Mechanism. The Parties agree that the procedures set forth in this ARTICLE 14 shall be the exclusive mechanism for resolving any dispute, controversy, or claim between the Parties that may arise from time to time under or in connection with this Agreement relating to any Party's rights or obligations hereunder (collectively, "Disputes") that is not resolved through good faith negotiation between the Parties.
- 14.2 Resolution by Executive Officers. Except as otherwise provided in this Agreement, in the event of any Dispute the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves including between their respective Chairmen In the event that such Dispute is not resolved on an informal basis within [***], either Party may, by written notice to the other Party, refer the Dispute to the other Party for attempted resolution by good faith negotiation between the chief executive officers of the Parties within [***] after such notice is received. Any Disputes shall be referred to the chief executive officers for attempted resolution. Except as set forth in Section 14.4 or 14.5, each Party may, in its sole discretion, seek resolution of any and all Disputes that are not resolved under this Section 14.2 in accordance with Section 14.3.

- 21 -

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- 14.3 Arbitration. Should the Parties fail to reach a resolution under Section 14.2, the Dispute will be finally settled under the Rules of Arbitration of the International Chamber Commerce by one or more arbitrators appointed in accordance with such Rules of Arbitration. The place of arbitration shall be Paris, France. The language of the proceedings shall be English. The decision or award of the arbitral tribunal shall be final, conclusive and binding upon both Parties, shall not be appealable, and shall be enforceable in any court of competent jurisdiction. The Parties agree that, any provision of applicable law notwithstanding, they will not request and the arbitrator(s) shall have no authority to award punitive or exemplary damages against either Party. The costs of the arbitration, including administrative and arbitrator's fees, shall be shared equally by the Parties. Each Party shall bear the cost of its own attorneys' fees and expert witness fees. Nothing in this Section shall preclude either Party from seeking interim or provisional relief in the form of a temporary restraining order, preliminary injunction, or other interim relief concerning a dispute prior to or during an arbitration pursuant to this Section necessary to protect the interests of such Party.
- 14.4 Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.
- 14.5 Patent Disputes. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any patent shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent laws of such country.
- 14.6 Confidentiality. Any and all activities conducted under Sections 14.2 through 14.5, including any and all proceedings and decisions of arbitrator(s) under Section 14.3, shall be deemed Confidential Information of each of the Parties, and shall be subject to ARTICLE 8.

ARTICLE 15

MISCELLANEOUS PROVISIONS

15.1 Events of Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to be in default under or in breach of any provision of this Agreement for failure or delay in fulfilling or performing any obligation under this Agreement (except with respect to payment obligations due under this Agreement) when such failure or delay is due to force majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, force majeure shall be defined as causes beyond the control of the Party, including acts of God; acts, regulations, or laws of any government; war; terrorism; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion, or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event, Licensee or LFB USA, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled and for 30 days thereafter. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any force majeure.

- 22 -

15.2 Notices. Any notice, request, demand, waiver, consent, approval or other communication which is required or permitted to be given to any Party shall be in writing and shall be deemed given only if delivered to the Party personally or sent to the Party by next Business Day delivery by an internationally recognized air courier service, or by certified mail (return receipt requested), with postage and registration or certification fees thereon prepaid, addressed to the Party at its address set forth below:

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rEVO Biologics, Inc.

175 Crossing Blvd.

Framingham, MA 01702

Attention: President

Fax: 508-370-3797

E-mail: yann.echelard@revobiologics.com

LFB USA:

LFB USA, Inc.

175 Crossing Blvd.

Framingham, MA 01702

Attention: President

Phone: 508-370-5100

E-mail: william.gavin@lfb-usa.com

or to such other address as such Party may from time to time specify by notice given in the manner provided herein to each other Party entitled to receive notice hereunder.

- 15.3 Entire Agreement. This Agreement (including any Annexes, Schedules, Exhibits or other attachments hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written statement may be used to interpret or vary the meaning of the terms and conditions hereof. This Agreement supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof.
- 15.4 Assignment. Neither Party may assign or otherwise transfer this Agreement without the prior written consent of the other Party. Assignment of this Agreement by either Party shall not relieve the assignor of its obligations hereunder. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.
- 15.5 Headings. The descriptive headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of the Agreement.
- 15.6 Independent Contractor. Each Party shall be acting as an independent contractor in performing under this Agreement and shall not be considered or deemed to be an agent, employee, joint venturer or partner of the other Party.

- 23 -

- 15.7 Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any law or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party.
- 15.8 Compliance with Laws. In performing under this Agreement, each Party shall comply with all Applicable Laws affecting this Agreement.
- 15.9 Export Controls. Licensee and its Affiliates and sublicensees shall comply with all Applicable Laws controlling the export of certain commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified

countries. Licensee hereby gives written assurance that it will comply with, and will cause its Affiliates and sublicensees to comply with, all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or its Affiliates or sublicensees, and that it will indemnify and hold LFB USA harmless for the consequences of any such violation.

15.10 Amendment. This Agreement may not be amended or modified except by an instrument in writing signed by authorized representatives of all Parties.

15.11 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. This Agreement has been prepared in the English language and the English language shall control its interpretation. Any and all litigation or other proceedings regarding the Agreement shall be conducted in the English language.

15.12 Waiver of Jury Trial. EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT.

15.13 Counterparts. This Agreement may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Agreement.

15.14 No Waiver. The failure of either Party to enforce at any time for any period the provisions of or any rights deriving from this Agreement shall not be construed to be a waiver of such provisions or rights or the right of such Party thereafter to enforce such provisions.

15.15 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

- 24 -

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15.16 Interpretation. In this Agreement unless otherwise specified (i) "includes" and "including" shall mean includes and including without limitation; (ii) a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking; (iii) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted; (iii) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders; (iv) the Schedules and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the recitals and the Schedules and attachments; the headings in this Agreement are for information only and shall not be considered in the interpretation of this Agreement; and (v) general words shall not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things.

[SIGNATURES FOLLOW ON NEXT PAGE]

- 25 -

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above by their respective duly authorized officers.

rEVO BIOLOGICS, INC.

/s/ Yann Echelard

Name: Yann Echelard

Title: President

LFB USA, INC.

/s/ William Gavin

Name: William Gavin

Title: President

- 26 -

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Schedule 1.30

Licensed Patent Rights

[***]

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Schedule 1.47

THIRD PARTY IN-LICENSE AGREEMENTS

[***]