UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of July 2021

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, C8
SE-111 22
Stockholm, Sweden
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On July 21, 2021, Calliditas Therapeutics AB ("Calliditas") entered into a licensing agreement with STADA Arzneimittel AG ("STADA"). Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of 20 million euros upon signing and up to an additional 77.5 million euros in future payments linked to pre-defined regulatory and commercialization milestones. STADA is also obligated pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties. The partnership relates to a novel oral formulation of a potent and well-known active substance – budesonide – designed to target down regulation of IgA1 with a view to be disease modifying.

A copy of the agreement is attached hereto as Exhibit 10.1 and is incorporated herein by reference. The foregoing description of the agreement does not purport to be complete and is qualified in its entirety by reference to such exhibit. The Company hereby incorporates by reference the information set forth above and in Exhibit 10.1 into the Company's registration statement on Form F-3 (File No. 333-257851).

On July 21, 2021, the Company issued a press release announcing the agreement, a copy of which is attached here to as Exhibit 99.1. The information contained in Exhibit 99.1 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

EXHIBIT INDEX

Exhibit	Description
10.1*	Commercialization Agreement dated as of July 21, 2021, by and between the Company and parties named therein
99.1	Company announcement dated July 21, 2021

*Certain portions of this exhibit (indicated by "[***]") have been omitted as we have determined they are both not material and are the type that the Company treats as private or confidential.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLIDITAS THERAPEUTICS AB

Date: July 23, 2021

By: /s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer

Exhibit 10.1

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

COMMERCIALIZATION AGREEMENT

BETWEEN

CALLIDITAS THERAPEUTICS AB

AND

STADA ARZNEIMITTEL AG

Dated July 21, 2021

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COMMERCIALIZATION AGREEMENT

This COMMERCIALIZATION AGREEMENT (this "**Agreement**") is made and effective as of July 21, 2021 (the "**Effective Date**") by and among **Calliditas Therapeutics AB**, a company organized under the laws of Sweden, with company registration number 556659-9766 and its registered office and mailing address at PO Box 70351, SE-107 24 Stockholm, Sweden and its principal office and address for courier delivery at Kungsbron 1, C8, SE-111 22 Stockholm, Sweden ("**Calliditas**") and STADA Arzneimittel AG**,** a company organized under the laws of Germany, with a registered office at Stadastrasse 2-18, 61118 Bad Vilbel, Germany ("**Partner**") (each of Calliditas and Partner being a "**Party**," and collectively, the "**Parties**").

WHEREAS, Calliditas has developed a pharmaceutical product, which consists of a proprietary oral formulation of budesonide targeted for delayed and sustained release in the small intestine. Calliditas has designed and completed certain successful clinical trials for the Product (as defined below), established manufacturing methodologies and capabilities for the Product, prepared and filed certain Regulatory Submissions (as defined below), and developed and owns, or has exclusive rights to, certain patents and know-how relating to the Product;

WHEREAS, Partner desires to obtain a license to commercialize, distribute, import and sell the Product in the Partner Territory (as defined below) and to obtain the supply of the Product from Calliditas, and Calliditas is willing to grant such license and provide such supply on the terms and conditions set forth below and the Supply Agreement; and

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

ARTICLE 1

DEFINITIONS

The following terms, whether used in the singular or the plural, shall have the meanings designated to them under this Article, unless otherwise specifically indicated.

1.1 "**Acquirer**" means, collectively, with respect to a Change of Control of a Party, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.2 "**Affiliate**" means any Person controlled by, controlling, or under common control with a Party. For purposes of the definition of "Affiliate," "control" and, with corresponding meanings, the terms "controlled by," "controlling," and "under common control with" means (a) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities, participating profit interest, or other ownership interests of a legal entity, or (b) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance.

1.3 "**Agreement**" has the meaning set forth in the Preamble.

1.4 "**Alliance Manager**" has the meaning set forth in Article 4.1(a).

1.5 "**Applicable Laws**" means applicable federal, national, foreign, supranational, state, provincial or local or administrative statute, law, ordinance, rule, code or regulation or orders, injunctions, decrees of any court, administrative agency or similar authority.

1.6 "**Applicable Senior Officers**" means with respect to Partner, its Senior Executive Officer or the respective competent Executive Vice President, and with respect to Calliditas, its Chief Executive Officer.

1.7 "**Budesonide**" means (a) the compound described as budesonide(16α,17-[(*RS*)-Butan-1,1-diyldioxy]-11β,21-dihydroxypregna-1,4-dien-3,20-dion) or (b) any [***] of the foregoing (a), or any combination thereof.

1.8 "**Business Day**" means any day except (a) Saturday, (b) Sunday or (c) a day that is a public holiday in Stockholm, Sweden or Bad Vilbel, Germany.

1.9 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1; provided that the first Calendar Quarter of the Term will commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter will end on the last day of the Term.

1.10 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31; provided that the first Calendar Year of the Term will commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs, and the last Calendar Year will end on the last day of the Term.

1.11 "**Calliditas**" has the meaning set forth in the Preamble.

1.12 "**Calliditas Confidential Information**" has the meaning set forth in Article 8.1.

1.13 "**Calliditas Indemnitees**" has the meaning set forth in Article 11.1.

1.14 "**Calliditas Territory**" means all countries of the world other than the Partner Territory.

1.15 "**Calliditas Trademarks**" means the trademark applications and registrations filed with the EMA for the Product and identified in **Schedule 1**.

1.16 "**Change of Control**" means, with respect to a Party, (i) a merger or consolidation involving such Party, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the outstanding securities or other ownership interests of the surviving entity immediately after such merger, reorganization or consolidation, (ii) a transaction or series of related transactions in which a Third Party, together with its Affiliates (determined as of immediately prior to the closing of the first such transaction), becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities or other ownership interests of such Party, or (iii) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets, but excluding with regard to (i) to (iii) [***].

1.17 "**Claims**" has the meaning set forth in Article 11.1.

1.18 "**Clinical Trial**" means any clinical studies and tests in human subjects of the Product or any Combination or Combined Dosage Therapy Product.

1.19 "**Combination or Combined Dosage Therapy Product**" means a pharmaceutical product consisting of both (a) a Product and (b) [***].

1.20 "**Commercialization**" means, with respect to the Product or a Combination or Combined Dosage Therapy Product, any and all activities directed to marketing, promoting, distributing, importing for commercial sale, using for commercial purposes, offering to sell, selling or having sold such product, including conduct of medical affairs activities and commercial activities conducted in preparation for launch of such product, including secondary packaging, labeling and serialization and activities directed to obtaining (as applicable) and maintaining Regulatory Approval and also obtaining and maintaining the Unconditional Regulatory Approval, but not including Manufacturing. "**Commercialize**" and "**Commercialized**" have a correlative meaning.

1.21 "**Commercialization Plan**" has the meaning set forth in Article 5.2.

1.22 "**Commercially Reasonable Efforts**" means [***].

1.23 "**Competing Product**" means any pharmaceutical product (other than the Product) that [***].

1.24 "**Competitive Infringement**" means the making, using, selling, offering for sale, or importing, by any Third Party (other than any Third Party authorized by a Party with respect to the Product), of any pharmaceutical product that is Covered by any Valid Claim of any Licensed Patent or Patent within New Calliditas IP. For the avoidance of doubt, filing of an Abbreviated New Drug Application, or equivalent action outside of the United States that would constitute an act of patent infringement under Applicable Laws, with any applicable Governmental Authority with respect to a Product as the reference product by any such Third Party will be deemed to be Competitive Infringement.

1.25 "**Conditional Regulatory Approval**" means a Regulatory Approval granted according to Art. 14 (7) Council Regulation (EC) No 726/2004.

1.26 "**Confidential Information**" has the meaning set forth in Article 8.1.

1.27 "**Controlled**" means, with respect to any Patents or item of Know-How or other right, that a Party or such Party's Affiliate (other than Excluded Partner Affiliates) owns or has a license to such item or right (other than pursuant to this Agreement) and has the ability to grant to the other Party a license, sublicense, or rights of access and use under such item or right as provided for in this Agreement without violating the terms or conditions of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access and use; provided that if there is a Change of Control of a Party during the Term, such Party will be deemed not to Control any Patents, Know-How or other right that is owned or in-licensed (prior to the closing of such Change of Control or at any time thereafter) by the Acquirer of such Party, unless such Party has in-licensed any such Patents, Know-How or other right from the Acquirer prior to the closing of such Change of Control. "**Control**" has a correlative meaning.

1.28 "**Cover**" means, with respect to a given product and a given Patent in a given country, that, absent a license hereunder, the sale, offer for sale or importation of such product in such country would infringe a claim of such Patent, or in the case of a Patent that is a pending patent application, would infringe a claim pending in such patent application if it were to issue as a patent. "**Covering**" and "**Covered**" have a correlative meaning.

1.29 "**Development**" means to discover, research or otherwise develop a process, compound or product, including conducting non-clinical, pre-clinical and clinical research and development activities, including toxicology, pharmacology and other pre-clinical development efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, clinical studies (including Clinical Trials and pre-approval studies), regulatory affairs and clinical study regulatory activities. Notwithstanding the foregoing, "Development" excludes (a) Commercialization and (b) Manufacture. "**Develop**" and "**Developed**" have a correlative meaning.

1.30 "**Development Milestone Event**" has the meaning set forth in Article 6.2(a).

1.31 "**Development Milestone Payment**" has the meaning set forth in Article 6.2(a).

1.32 "**Disclosing Party**" has the meaning set forth in Article 8.1.

1.33 "**Dispute**" has the meaning set forth in Article 13.11(a).

1.34 "**Effective Date**" has the meaning set forth in the Preamble.

1.35 "**EEA**" or "**European Economic Area**" means the means the organization of member states as it may be constituted from time to time, which as of the Effective Date consists of the EU member states and Iceland, Liechtenstein and Norway.

1.36 "**EMA**" means the European Medicines Agency.

1.37 "**ERA**" has the meaning set forth in Article 2.2(b).

1.38 "**European Union**" or "**EU**" means the organization of member states as it may be constituted from time to time, which as of the Effective Date consists of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

1.39 "**Excluded Partner Affiliate**" means, with regard Partner, [***].

1.40 "**FD&C Act**" means the U.S. Federal Food, Drug, and Cosmetics Act (21 U.S.C. Section 301 *et seq*.), as amended.

1.41 "**FDA**" means the U.S. Food and Drug Administration.

1.42 "**Field**" means all therapeutic uses of the Product, in the indication of IgA nephropathy, whether as monotherapy or in form of a Combination or Combined Dosage Therapy Product.

1.43 "**First Commercial Sale**" means, with respect to the Product and a country in the Partner Territory, the first sale, transfer or disposition for value by or on behalf of Partner or any of its Affiliates to a Third Party in such country after Regulatory Approval for such Product has been obtained in such country, or, as applicable and permitted in such country before such Regulatory Approval has been obtained, pursuant [***]. A First Commercial Sale excludes any transfer or other distribution of the Product as promotional sample to physicians or hospitals in amounts consistent with industry practice and consistent with prevailing industry standards, or of a Product transferred or disposed at no charge for research, preclinical, clinical, or regulatory purposes or in connection with patient assistance, compassionate use, "right-to-try" use, indigent programs or other charitable purposes (in each case except to the extent reimbursed by a third-party payor) or of a Product for investigator-initiated trials or on a named patient basis.

1.44 "**FTE Costs**" means, with respect to a period, the FTE Rate times the number of FTEs, or portion thereof, actually utilized in performing activities under this Agreement during such period.

1.45 "**FTE Rate**" means a rate of [***] EUR per FTE per year. The FTE Rate is "fully burdened" and will include employee salaries and all overhead allocated to such employee's work hereunder. FTE as used in this definition means the equivalent of a full-time individual's work for a twelve (12) month period (consisting of [***] hours per year).

1.46 "**Future Commercialization Transaction**" has the meaning set forth in Article 12.3(i).

1.47 "**GDPR**" means the General Data Protection Regulation (EU) 2016/679.

1.48 "**Generic Version**" means, with respect to the Product, a product that is granted Regulatory Approval in the relevant country of the Partner Territory after the Effective Date and is (a) determined by the applicable Regulatory Authority or by Applicable Law in the relevant country of the Partner Territory to be "comparable," or "interchangeable" to the Product and can be prescribed for use in [***], or (b) [***].

1.49 "**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

1.50 "**Improved Product**" means [***]. "Improved Product" includes in particular [***], but excludes any [***].

1.51 "**Improvements**" means [***].

1.52 "**Indemnitee**" has the meaning set forth in Article 11.2.

1.53 "**Indemnitor**" has the meaning set forth in Article 11.2.

1.54 "**Initiating Party**" has the meaning set forth in Article 7.5(c).

1.55 "**Insolvency Event**" means (a) a Party suspends payment of its debts or admits inability to pay its debts, or is deemed unable to pay its debts within the meaning of Applicable Law; (b) a Party commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with any class of its creditors generally; (c) in relation to a Party, a petition is filed, a notice is given, a resolution is passed or an order is made, for or in connection with the winding up of a Party; (d) an application is made to court, or an order is made, for the appointment of an administrator, or a notice of intention to appoint an administrator is given or an administrator is appointed, over a Party; (e) a receiver is appointed over all or any of the assets of a Party; or (f) any analogous demand, appointment or procedure is instituted or occurs in relation to a Party in any jurisdiction in which the Party carries on business.

1.56 "**JSC**" has the meaning set forth in Article 4.1.

1.57 "**Know-How**" means and includes conceptions, ideas, reductions-to-practice, innovations, inventions, trade secrets, technology, processes, practices, formulae, instructions, procedures, assembly procedures, results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data, including study designs and protocols), machines, equipment, compositions of matter, compounds, formulations, genetic material, improvements, enhancements, modifications, technological developments, know-how, methods, treatments, techniques, systems, designs, artwork, drawings, plans, specifications, documentation, data and information, customer lists, textual or graphical works, packaging, marketing materials, display material, logos and slogans, in each case whether or not confidential, proprietary, patentable, copyrightable, or susceptible to any other form of legal protection (whether registered or not), in written, electronic or any other form.

1.58 "**Licensed Intellectual Property**" means, collectively, the Licensed Patents and the Licensed Know-How.

1.59 "**Licensed Know-How**" means, subject to Article 3.6, any and all Know-How Controlled by Calliditas or any of its Affiliates (solely or jointly with any Third Party) as of the Effective Date or during the Term, and which is [***].

1.60 "**Licensed Patents**" means, subject to Article 3.6, any and all Patents in the Partner Territory Controlled by Calliditas or any of its Affiliates (solely or jointly with any Third Party) as of the Effective Date or during the Term, which (a) [***]; and (b) [***]. The Licensed Patents as of the Effective Date are identified in **Schedule 3**. Licensed Patents [***].

1.61 "**Losses**" has the meaning set forth in Article 11.1.

1.62 "**MAA**" means a Marketing Authorization Application filed with the EMA under the centralized European procedure (including amendments and supplements thereto) in respect of the Product in the Field.

1.63 "**Major Market Countries**" means [***].

1.64 "**Manufacture**" means all activities related to the making, having made, production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Product or a Combination or Combined Dosage Therapy Product, including [***], but excluding [***]. "**Manufactured**" and "**Manufacturing**" have a correlative meaning.

1.65 "**Minimum Royalties**" has the meaning set forth in Article 6.5(e).

1.66 "**Net Sales**" means, with respect to the Product, the gross amount invoiced by Partner or its Affiliates for the sale or supply of such Product to a Third Party (including distributors), less only the following deductions (without duplications) to the extent appropriately allocated to the sale of such Product in accordance with Partner's or its Affiliates' accounting standards as consistently applied, and actually taken, paid, accrued, or allowed, or included in the gross sales prices or specifically allocated in its financial statements with respect to such sales of Product:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]; and

(f) [***].

Notwithstanding the foregoing:

(i) Sales between Partner and its Affiliates shall be disregarded for purposes of calculating Net Sales unless there is no subsequent sale of the Product to a Third Party.

(ii) [***].

(iii) [***].

(iv) [***].

Net Sales exclude [***].

[***].

1.67 "**New Calliditas IP**" has the meaning set forth in Article 7.3(a).

1.68 "**New Joint IP**" has the meaning set forth in Article 7.3(c).

1.69 "**New Partner IP**" has the meaning set forth in Article 7.3(b).

1.70 "**Non-Initiating Party**" has the meaning set forth in Article 7.5(c).

1.71 "**Ongoing Clinical Trial**" means NefIgArd, Calliditas' global pivotal Phase 3 Clinical Trial and the related open label extension Clinical Trial in primary IgA nephropathy on-going as of the Effective Date.

1.72 "**Orphan Designation**" means the orphan designation EU/3/16/1778 granted by the European Commission on 18 November 2016.

1.73 "**Partner**" has the meaning set forth in the Preamble.

1.74 "**Partner Confidential Information**" has the meaning set forth in Article 8.1.

1.75 "**Partner Controlled Patents**" has the meaning set forth in Article 7.4(c).

1.76 "**Partner Indemnitees**" has the meaning set forth in Article 11.1.

1.77 "**Partner Initial Commercialization Plan**" means the commercialization plan to be provided by Partner to Calliditas pursuant to Article 5.3.

1.78 "**Partner Territory**" means the EEA, the United Kingdom and Switzerland.

1.79 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.80 "**Patent**" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)).

1.81 "**Patent Challenge**" has the meaning set forth in Article 12.2(d).

1.82 "**Person**" means any individual, corporation, partnership (whether general, limited or limited liability), joint-stock company, unincorporated organization or other legal entity having legal personality or the right to sue in its own name.

1.83 "**Pharmacovigilance Agreement**" has the meaning set forth in Article 2.11.

1.84 "**PIP**" has the meaning set forth in Article 2.5(a).

1.85 "**Pricing Approval**" means all approvals, agreements, determinations, or decisions establishing prices that can be charged to end users or consumers for the Product or that shall be reimbursed by Regulatory Authorities for a Product, in each case that are necessary for effective market access and generally obtained before commercial product launch in a country in the Territory where Regulatory Authorities approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.86 "**Product**" means (a) Budesonide modified release 4 mg capsules being studied in the Ongoing Clinical Trial, in all presentations and package configurations, and (b) any Improved Product [***].

1.87 "**Product Income**" means [***].

1.88 "**Quality Agreement**" has the meaning set forth in Article 5.1.

1.89 "**Receiving Party**" has the meaning set forth in Article 8.1.

1.90 "**Regulatory Approval**" means, for the Product with respect to a country in the Territory, all permissions, approvals, licenses, registrations, authorizations, or clearances of any Regulatory Authority that are necessary for the sale of such Product in such country in the Territory, including approval of the MAA.

1.91 "**Regulatory Authority**" means any domestic (federal or state), supranational or foreign court, commission or governmental, regulatory or administrative body, board, bureau, agency, instrumentality, authority or tribunal or any subdivision thereof, and the authority/authorities in each country in the Territory that have responsibility for granting regulatory approval for the Manufacture or Commercialization of Product in each of such country, or for Pricing Approvals.

1.92 "**Regulatory Exclusivity Period**" means with respect to any country in the Partner Territory, a period of exclusivity (other than Patent exclusivity), granted by Applicable Laws or by a Regulatory Authority in respect of such country, which either confers exclusive marketing rights with respect to a product or prevents another party from using or otherwise relying on the data supporting the approval of the Regulatory Approval for a product without the prior written authorization of the Regulatory Approval-holder, as applicable, such as new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, non-patent-related pediatric exclusivity, or any other applicable marketing or data exclusivity, including any such periods under national implementations in the EU of Article 8 of Directive 2001/83/EC, Article 14(11) of Parliament and Council Regulation (EC) No 726/2004, Parliament and Council Regulation (EC) No 141/2000 on orphan medicines, Parliament and Council Regulation (EC) No 1901/2006 on medicinal products for pediatric use and all international equivalents.

1.93 "**Regulatory Requirements**" means (a) all specifications, methods of Manufacture (or packaging, labelling or serialization) and other information in one or more Regulatory Submissions related in any way to the Product, and (b) all Applicable Laws, applicable regulatory guidance documents, and other requirements of any Regulatory Authority that govern the Product, including its Manufacture (or packaging, labelling or serialization), including but not limited to the requirements set forth in Council Regulation (EC) No 726/2004, Directive 2001/83/EC or any implementing or complementing national regulation, and the respective GMP Guidelines, and in each case, the foreign equivalents thereof, as any of the foregoing may be amended from time to time.

1.94 "**Regulatory Submissions**" means all applications, filings, briefing books, dossiers and the like submitted to a Regulatory Authority for the purpose of obtaining Regulatory Approval or a Pricing Approval from that Regulatory Authority.

1.95 "**Representatives**" has the meaning set forth in Article 8.4.

1.96 "**Right of First Negotiation**" has the meaning set forth in Article 3.8(b).

1.97 "**Royalty Rate**" has the meaning set forth in Article 6.3.

1.98 "**Royalty Term**" has the meaning set forth in Article 6.4.

1.99 "**Sales Milestone Event**" has the meaning set forth in Article 6.2(c).

1.100 "**Sales Milestone Payment**" has the meaning set forth in Article 6.2(c).

1.101 "**SmPC**" has the meaning set forth in Article 6.5(a).

1.102 **"Stand-Still-Fee"** has the meaning set forth in Article 5.8(b).

1.103 "**Supply Agreement**" has the meaning set forth in Article 5.1.

1.104 "**Tax**" or "**Taxes**" means any (a) all federal, provincial, territorial, state, municipal, local, foreign or other taxes, imposts, rates, levies, assessments and other charges in the nature of a tax (and all interest and penalties thereon and additions thereto imposed by any Governmental Authority), including all income, excise, franchise, gains, capital, real property, goods and services, transfer, value added, gross receipts, windfall profits, severance, ad valorem, personal property, production, sales, use, license, stamp, documentary stamp, mortgage recording, employment, payroll, social security, unemployment, disability, escheat, estimated or withholding taxes, and all customs and import duties, together with all interest, penalties and additions thereto imposed with respect to such amounts, in each case whether disputed or not; (b) any liability for the payment of any amounts of the type described in clause (a) as a result of being or having been a member of an affiliated, consolidated, combined or unitary group; and (c) any liability for the payment of any amounts as a result of being party to any tax sharing agreement or arrangement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in clause (a) or (b).

1.105 "**Term**" has the meaning set forth in Article 12.1.

1.106 "**Territory**" means (a) with respect to Partner, the Partner Territory and (b) with respect to Calliditas, the Calliditas Territory.

1.107 "**Third Party**" means any Person other than Calliditas, Partner and their respective Affiliates.

1.108 "**Unconditional Regulatory Approval**" means a Regulatory Approval granted in accordance with Art. 14 (1) Council Regulation (EC) No 726/2004.

1.109 "**Valid Claim**" means, with respect to a particular country and the Product, (a) a claim of an issued and unexpired Licensed Patent (other than a utility model or design right) that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental authority of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal and (ii) has not been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) a claim which (i) is pending in a patent application included in the Licensed Patents (other than an application for a utility model or design right) in such country less than [***] from the earliest date on which such patent application claims priority, and (ii) has been prosecuted in good faith and has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken; and, in each case of such an issued or pending claim pursuant to (a) or (b), [***].

ARTICLE 2

CLINICAL DEVELOPMENT AND REGULATORY APPROVAL

2.1 Ongoing Clinical Trial. Calliditas shall, at its sole cost, complete the Ongoing Clinical Trial except to the extent that it is not able to do so due to any safety issue or regulatory restriction or other circumstances outside the control of Calliditas and its Affiliates. Notwithstanding the provisions of Article 2.9, Calliditas shall keep Partner informed of the status and progress of the Ongoing Clinical Trial through the JSC. Calliditas shall provide to Partner all clinical study reports and related documentation with respect to the Ongoing Clinical Trial and, notwithstanding the provisions of Article 3.5, any Know-How arising in connection with the conduct of the Ongoing Clinical Trial as soon as practically possible.

2.2 EMA Marketing Authorization Application.

(a) Calliditas has, at its sole cost, submitted an application for Conditional Regulatory Approval, including an Orphan Designation maintenance report, in the name of Calliditas in respect of the Product. Calliditas has used and will use Commercially Reasonable Efforts to obtain Conditional Regulatory Approval and to maintain the Orphan Designation. Notwithstanding the provisions of Article 2.9, Calliditas shall keep Partner informed of the status and progress of the MAA through the JSC.

(b) For the purposes of the MAA, Calliditas has, at its sole cost acquired access to an environmental risk assessment ("**ERA**") of the Product and provided this ERA data to the competent Regulatory Authority.

2.3 Transfer of Conditional Regulatory Approval and Orphan Designation.

(a) Promptly after first grant of Conditional Regulatory Approval for the Product, Calliditas shall, at its sole cost, file with the EMA all documentation necessary for the European Commission to transfer the rights and obligations related to being the market authorization holder in respect of the Product in the territory under the jurisdiction of the EMA, to Partner. The Parties shall cooperate and promptly take all such actions reasonably necessary or desirable, with each Party bearing its own expenses, in order to procure the prompt transfer of the same to Partner. Notwithstanding any other provision of this Agreement: (i) Partner shall not market or sell the Product in the Partner Territory prior to completion of such transfer to Partner, except where Partner may lawfully distribute the Product before such transfer, in which case Calliditas will support Partner and take all necessary steps allowing Partner to assume the role of distributor; and (ii) Partner shall not assign or transfer any Regulatory Approval other than (x) to an Affiliate of Partner (other than an Excluded Partner Affiliate) or (y) where required by local laws to have the Product distributed by a distributor, to that distributor of Partner, and only for so long as such entity remains an Affiliate or distributor of Partner. After the successful transfer of the transfer to Partner pursuant to this Article of the rights and obligations related to being the market authorization holder, except as expressly set out in this Agreement, Partner shall be solely responsible for the compliance with and performance of any and all obligations (including any regulatory filings, updates and safety data reporting) related to being the market authorization holder in respect of the Product in the territory under the jurisdiction of the EMA, irrespective of any assignments and transfers.

(b) Promptly after grant of Conditional Regulatory Approval for the Product, Calliditas shall, at its sole cost, file with the EMA all documentation necessary to transfer the Orphan Designation to Partner in accordance with Art. 5 (11) Council Regulation (EC) No 141/2000 on orphan medicines. The Parties shall cooperate and promptly take all such actions reasonably necessary or desirable, with each Party bearing its own expenses, in order to procure the prompt transfer of the Orphan Designation to Partner. Notwithstanding any other provision of this Agreement, Partner shall not assign or transfer the Orphan Designation to any Third Party other than (x) to an Affiliate of Partner (other than an Excluded Partner Affiliate) or (y) where required by local laws to have the Product distributed by a distributor, to that distributor of Partner, and only for so long as such entity remains an Affiliate or distributor of Partner. After the successful transfer of the Orphan Designation to Partner, except as expressly set out in this Agreement, Partner shall be solely responsible for compliance with and performance of any and all obligations related to upholding the Orphan Designation or orphan status in the Partner Territory.

(c) [***].

2.4 Partner Territory Regulatory Submissions. Partner shall, at its sole cost:

(a) promptly after issue by Calliditas of the final clinical study report in respect of the Ongoing Clinical Trial and after successful transfer of the Conditional Regulatory Approval and the Orphan Designation to Partner, apply for Unconditional Regulatory Approval in respect of the Product in the Field from the EMA; and

(b) apply Commercially Reasonable Efforts to make all filings and notifications in connection with, and obtain and maintain, all Pricing Approvals in each country of the Partner Territory; and

(c) after issue by Calliditas of the final clinical study report in respect of the Ongoing Clinical Trial, use Commercially Reasonable Efforts to obtain and maintain Regulatory Approval in each country of the Partner Territory in which approval of the MAA does not authorize sale of the Product (including the United Kingdom and Switzerland).

2.5 Development by Parties; Paediatric Investigation Plan.

(a) Any Development activities that are necessary to obtain and maintain Regulatory Approval for the Product in the Field in each country of the Partner Territory, shall be thoroughly defined and divided between the Parties through the JSC (building on the significant preparations already undertaken by Calliditas with regards to the design and execution of the PIP) provided that:

(i) [***]; and

(ii) [***].

(b) Partner agrees to cover any costs incurred by Calliditas in connection with conducting the PIP in the amount of up to [***]. Any additional PIP-related costs, in particular resulting from a required change of the protocol, shall be subject to a cost sharing model and further discussed between the Parties through the JSC.

2.6 Clinical Development by Partner. Notwithstanding any other provision of this Agreement, Partner (and its Affiliates (other than Excluded Partner Affiliates) and Third Parties authorized or assisted by Partner) shall not conduct a Clinical Trial without the prior written consent of Calliditas. Prior to seeking regulatory approval for or initiating any Clinical Trial or permitting an Affiliate or Third Party to do so (whether before or after grant of Regulatory Approval of the Product), Partner shall notify Calliditas of its intention (or that of Partner's Affiliates or such Third Parties) to conduct a Clinical Trial, and provide a detailed synopsis and protocol of such Clinical Trial to the Alliance Manager, CMO and CEO of Calliditas. Calliditas shall be deemed to have given its consent to the conduct of a Clinical Trial in accordance with the provided protocol upon the expiry of thirty (30) Business Days after receipt by Calliditas (as above) of the protocol unless Calliditas notifies Partner in writing during such period that consent is not granted. Calliditas may withhold its consent to the conduct of a Clinical Trial in good faith on the grounds that the proposed Clinical Trial [***].

2.7 Assistance from Calliditas. Calliditas shall, at the reasonable request of Partner, provide to Partner information (but excluding information relating to Manufacture of the Product) within the Control of Calliditas that is necessary for Partner to prepare, file applications for, obtain and maintain Regulatory Approval for the Product as it exists at the Effective Date in each country of the Partner Territory provided that, except as provided in Article 2.1 and 2.2, Calliditas shall not be obliged to undertake any Development activities unless otherwise agreed by the Parties through the JSC.

2.8 Responsibility for Regulatory Interaction. Except as otherwise set out in this Article 2, as between the Parties (provided that Calliditas may have licensees in respect of the Product in the Calliditas Territory):

(a) Partner shall not take any action in connection with preparing, filing, obtaining and maintaining (x) Regulatory Approval for the Product in the Calliditas Territory, and (y) the Orphan Designation or orphan status (where applicable) for the Product in the Calliditas Territory;

(b) Partner shall have sole responsibility, at its own expense, (i) for maintaining the Conditional Regulatory Approval and Orphan Designation or orphan status once transferred to Partner, and (ii) for preparing, filing, obtaining and maintaining in Partner's name all Regulatory Approvals (excluding the Conditional Regulatory Approval) and Pricing Approvals for the Product in the Partner Territory;

(c) Without limitation to any other obligations of Partner, Partner shall at its own expense:

(i) take all steps necessary or desirable in a timely manner to maintain and renew any Regulatory Approval, and Pricing Approval and the Orphan Designation or orphan status in the Partner Territory; and

(ii) fulfil all obligations within all applicable timelines in connection with the Conditional Regulatory Approval (including, subject to Article 2.3(c), completing ongoing or new studies (other than the Ongoing Clinical Trial)), collecting additional data to confirm the Products benefit-risk balance remains positive, in each case as may be requested by any Regulatory Authority;

(d) Each Party shall be responsible for all communications and other dealings with the Regulatory Authorities within its respective Territory relating to the Regulatory Approvals and Pricing Approvals in its Territory; and

(e) for the avoidance of doubt, Partner shall be solely responsible for determining the prices for the Product in the Partner Territory, if and to the extent not restricted by the Applicable Laws, [***].

2.9 Mutual Cooperation.

(a) As soon as practically possible after receipt thereof, Calliditas shall provide material related to the regulatory review of Part A of the Ongoing Clinical Trial, including with respect to the application for Conditional Regulatory Approval and the maintenance of the Orphan Designation, to Partner and ask Partner to provide feedback. In essential communication with the Regulatory Authority or other strategic decisions to be made by Calliditas in connection with the Ongoing Clinical Trial, Calliditas shall consider in good faith said feedback provided by Partner, unless in particularly urgent cases where Calliditas cannot reasonably be expected to wait for such feedback.

(b) Partner shall, as marketing authorization holder, promptly notify Calliditas of all Regulatory Submissions, questions or enquiries as well as any material correspondence that it receives or plans to submit to a Regulatory Authority and shall promptly provide Calliditas with a full copy (which may be wholly or partly in electronic form) of the same. Promptly following receipt of any Regulatory Approval or other decision on a Regulatory Submission from a Regulatory Authority relating to the Product, Partner also shall furnish Calliditas with copies of the same (together with an English translation of the same, if applicable).

(c) Partner will keep Calliditas reasonably appraised of the status of any Regulatory Submissions related to the Product in the Partner Territory. Partner shall promptly notify Calliditas in writing upon receipt of any Regulatory Approval with respect to the Product in the Partner Territory. Partner will provide Calliditas with a report, not less than twenty (20) days after the end of each Calendar Quarter during the Term, describing in reasonable detail the status of all Regulatory Submissions and any applications, filings or notices made in connection with Pricing Approvals.

(d) Each Party shall, in connection with the other Party's interactions with Regulatory Authorities with respect to the Product in the other Party's Territory, (i) provide to the other Party such data or information within the first Party's control as is reasonably necessary or useful for such interactions; and (ii) cooperate with the other Party's reasonable requests related to such interactions at the requesting Party's cost.

(e) Each Party shall notify the other Party of: in the case of Partner, the principal issues raised in each material communication with Regulatory Authorities with respect to the Product; and in the case of Calliditas, the principal issues relevant to the activities of Partner under this Agreement that are raised in each material communication with the FDA with respect to the Product, within fifteen (15) Business Days after receipt thereof.

2.10 Regulatory Meetings. Apart from the process related to obtaining Unconditional Regulatory Approval of the Product, where specific processes will apply, Partner shall provide Calliditas with reasonable advance notice, including relevant documentation, of all substantive meetings with the Regulatory Authorities in the Partner Territory pertaining to the Product, or with as much advance notice as practicable under the circumstances. Partner otherwise shall use Commercially Reasonable Efforts to permit Calliditas to have, at Calliditas' expense, a representative of Calliditas attend, solely as a non-participating observer, substantive meetings with the Regulatory Authorities within the Partner Territory pertaining to the Product; provided, however, that if required by the Regulatory Authority or Partner and not requested by Calliditas, a representative of Calliditas shall attend such meeting and Calliditas' costs and expenses associated with such attendance shall be reimbursed by Partner. Partner shall promptly furnish Calliditas with relevant pre meeting documentation and copies of minutes of all meetings with a Regulatory Authority relating to the Product.

2.11 Adverse Event Reporting.

(a) Subject to Article 2.11(c), each Party shall be responsible for complying with all Regulatory Requirements and other legal requirements governing adverse events in its Territory.

(b) As promptly as practicable following the Effective Date, but in no event later than sixty (60) days or such longer period as may be mutually agreed by the Parties, thereafter, Partner and Calliditas will negotiate and agree upon safety data exchange procedures in a separate and detailed pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") and Partner shall not in any event sell or administer a Product to any human prior to the execution of the Pharmacovigilance Agreement. Such agreement will describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other safety problem of any significance, procedures for participation in the global safety database, and product quality and product complaints involving adverse events, sufficient to permit each Party and its Affiliates and partners or (sub-)licensees to comply with its legal obligations. The safety data exchange procedures will be promptly updated if required by changes in legal requirements. In the event of any conflict or inconsistency between this Agreement and the Pharmacovigilance Agreement with respect to: (i) safety-related matters, the Pharmacovigilance Agreement shall prevail; and (ii) any other matter, this Agreement shall prevail.

(c) Unless otherwise agreed by the Parties, Calliditas shall be responsible, itself or through a designee, for maintaining any required global safety database with respect to the Product.

ARTICLE 3

GRANT OF RIGHTS

3.1 License Grant by Calliditas.

(a) Subject to the terms and conditions of this Agreement, Calliditas, on behalf of itself and its Affiliates, hereby grants to Partner and its Affiliates (only for as long as they remain Affiliates of Partner and excluding Excluded Partner Affiliates):

(i) an exclusive, non-sublicensable license under the Licensed Intellectual Property solely to Commercialize (but excluding secondary packaging, labeling and serialization) the Product and, if applicable, a Combination or Combined Dosage Therapy Product, in each case in the Field in the Partner Territory; and

(ii) a non-exclusive, non-sublicensable license under the Licensed Intellectual Property to Develop, with respect to Improved Products only subject to Article 3.9, the Product and, if applicable, a Combination or Combined Dosage Therapy Product in the Field in the Partner Territory and through subcontractors in the Calliditas Territory (but not to conduct (aa) Clinical Trials without the consent of Calliditas pursuant to Article 2.6, (bb) Manufacturing Development (unless permitted pursuant to Article 3.1(d)) and (cc) any activities directed to obtaining Regulatory Approval for a Product or Combination or Combined Dosage Therapy Product in the Calliditas Territory); and

(iii) a non-exclusive non-sublicensable license under the Licensed Intellectual Property to conduct secondary packaging, labeling and serialization of Product purchased under or as permitted by the Supply Agreement and, if applicable, a Combination or Combined Dosage Therapy Product, in the Field in the Partner Territory and through subcontractors in the Calliditas Territory.

Partner shall remain responsible for the performance of its Affiliates under this Agreement and a breach of an obligation imposed on Partner hereunder as a result of breach by one of its Affiliates, shall be deemed to be a breach by Partner.

(b) Notwithstanding the foregoing, the exclusive rights granted under Article 3.1(a) shall not prevent the Development or Manufacture or secondary packaging, labeling or serialization of the Product or Combination or Combined Dosage Therapy Product by or on behalf of Calliditas or its Affiliates or its partners or licensees, in the Partner Territory, or the conduct of supply chain activities in respect of the same by or on behalf of Calliditas or its Affiliates or its partners or licensees, in the Partner Territory, for Commercialization outside the Partner Territory.

(c) Notwithstanding anything to the contrary, Partner shall have the right to engage Third Party (sub)contractors (including analytic laboratories, contract manufacturers and distributors) in the Partner Territory and the Calliditas Territory in connection with permitted Development, Manufacture or Commercialization of the Product and Combination or Combined Dosage Therapy Product in the Field in the Partner Territory for the benefit of Partner and to grant to such Third Party (sub)contractors all sublicenses required by it to perform the subcontracted tasks for the benefit of Partner, provided that (i) Partner shall ensure that such contractors are bound by legally binding and enforceable agreements under which all right, title and interest in and to all New Partner IP is solely and exclusively owned by Partner; and (ii) Partner shall remain responsible for the performance of such contractors under this Agreement and a breach of an obligation imposed on Partner hereunder as a result of breach by one of its contractors, shall be deemed to be a breach by Partner.

(d) Only as set out in:

(i) Article 3.1 of the Supply Agreement; or

(ii) Article 12.5(b)(ii) of this Agreement;

subject to the terms and conditions of this Agreement, Calliditas, on behalf of itself and its Affiliates, hereby grants and agrees to grant to Partner and its Affiliates (only for as long as they remain Affiliates of Partner and excluding Excluded Partner Affiliates) a non-exclusive, non-sublicensable license under the Licensed Intellectual Property to Manufacture the Product and, if applicable, a Combination or Combined Dosage Therapy Product, in each case in the Field in the Partner Territory or the Calliditas Territory, solely for Commercialization by Partner or its Affiliates in the Partner Territory in accordance with the terms of this Agreement. The provision by Calliditas to Partner of access to the Licensed Know-How relating to Manufacture of the Product, following grant of the licence pursuant to this Article 3.1(d) shall be as set out in the Supply Agreement, it being understood that [***]. Should such Manufacturing technology transfer be triggered by Article 12.5(b)(ii) of this Agreement, such Manufacturing technology transfer shall be initiated [***]. Should such Manufacturing technology transfer be triggered by Article 3.1 of the Supply Agreement, it shall be conducted diligently by the parties in such manner and at such point of time to enable, to the extent reasonably possible, Manufacturing of the Products on behalf of the Partner or by its designee without interruption.

3.2 License Grant by Partner

(a) Partner, on behalf of itself and its Affiliates (other than Excluded Partner Affiliates), hereby grants to Calliditas and its Affiliates a perpetual, irrevocable, fully paid-up, sub-licensable (including through multiple tiers) a non-exclusive license under the New Partner IP and Partner's share in New Joint IP solely as necessary for Calliditas (and its Affiliates and its and their licensees (including through multiple tiers) and contractors of the foregoing) to conduct (i) the Development, Manufacture and secondary packaging, labeling and serialization in the Field in the Partner Territory and in the Calliditas Territory, and (ii) Commercialization in the Field in the Calliditas Territory, in each of case (i) and (ii) above, of the Product (including any Improved Product, whether such is developed by Calliditas, by Partner or jointly by both Parties); and provided that any such use is consistent with the grant of licenses to Partner pursuant to Article 3.1, and without limitation to the provisions of Section 3.4(b).

(b) This un-blocking license is granted by Partner solely for the purpose to procure Calliditas' (and its Affiliates and its and their licensees (including through multiple tiers) and contractors of the foregoing) freedom to operate with regard to the Product in the Field in the Calliditas Territory. If Calliditas at any time wishes to exploit New Partner IP for any other purpose (e.g. for Development or Commercialization of a Combination or Combined Dosage Therapy Product), or to convert a non-exclusive license granted by Partner to an exclusive license, Calliditas shall request from Partner a respective license and in such event the Parties shall in good faith negotiate the terms of any such license, including reasonable consideration payable by Calliditas for such license.

3.3 Rights of Reference.

(a) Calliditas hereby grants to Partner and its Affiliates (other than Excluded Partner Affiliates), subject to the terms and conditions set forth in this Agreement, a "Right of Reference" as that term is defined in 21 C.F.R. § 314.3(b) (or any other similar provision under Applicable Law outside the US) to all regulatory documents, dossiers and filings Controlled by Calliditas or its Affiliates inside and outside the Partner Territory that relate to the Product, provided that such right shall be for the sole purpose of enabling Partner or its Affiliates (other than Excluded Partner Affiliates) to obtain and maintain Regulatory Approval with respect to the Product in the Partner Territory in the Field.

(b) Partner hereby grants to Calliditas and its Affiliates and its partners and licensees in respect of the Product outside the Partner Territory, subject to the terms and conditions set forth in this Agreement, a "Right of Reference" as that term is defined in 21 C.F.R. § 314.3(b) (or any other similar provision under Applicable Law outside the US) to all regulatory documents, dossiers and filings by Partner or its Affiliates (other than Excluded Partner Affiliates) that relate to the Product, provided that such right shall be for the sole purpose of enabling Calliditas and its Affiliates and its partners and licensees to obtain and maintain Regulatory Approval with respect to the Product outside the Partner Territory.

(c) Each Party shall provide a signed statement to give effect to the rights granted in this Article 3.3, if requested by the other Party.

3.4 Negative Covenants..

(a) Partner shall not, nor shall it cause or permit any of its Affiliates or any Third Party to (and shall procure that its Affiliates (other than Excluded Partner Affiliates) do not and require in its agreements with its contractors to the extent they need to perform acts permitted by, or to exploit rights granted under this Agreement that they do not), (i) use or practice, directly or indirectly, any Licensed Intellectual Property for any purposes other than as expressly permitted by this Agreement; nor (ii) directly or indirectly conduct any activities with respect to Product or a Combination or Combined Dosage Therapy Product (or Regulatory Approval of the same) outside the Field, it being understood that Partner shall be entitled to conduct (x) Development activities other than Clinical Trials and activities directed to obtaining Regulatory Approval both in the Partner Territory and in the Calliditas Territory to the extent provided in Article 3.1(a)(ii) and (y) Clinical Trials only subject to Article 2.6, whether in the Partner Territory or in the Calliditas Territory.

(b) During the Term, Partner shall not, nor shall it cause or permit any of its Affiliates or any Third Party to (and shall procure that its Affiliates (other than Excluded Partner Affiliates)do not and shall require in its agreements with its contractors to the extent they need to perform acts permitted by, or to exploit rights granted under this Agreement that they do not) Commercialize any solely Developed Improved Product or solely Developed Combination or Combined Dosage Therapy Product outside the Partner Territory unless it has first notified Calliditas of its intent to do so at a meeting of the JSC and, should Calliditas so request by notice [***] after such JSC meeting, negotiate exclusively with Calliditas in good faith for a period of at [***] regarding the grant to Calliditas of the exclusive right to conduct such Commercialization in such portions of the Calliditas Territory as nominated by Calliditas. With regard to Improved Products or Combination or Combined Dosage Therapy Products which are jointly developed by the Parties, the Parties shall agree on mutual rights, responsibilities and licenses in accordance with Article 3.9.

(c) Without limiting the generality of Article 3.4(a), and subject to Article 3.9, Partner is entitled, either itself or through any of its Affiliates or any Third Party, to promote, market, recommend, sell or supply or otherwise Commercialize Combination or Combined Dosage Therapy Product in the Partner Territory following Regulatory Approval in the Partner Territory which has been approved by the relevant Regulatory Authority in the Territory.

(d) Without limiting the generality of Article 3.4(a), Partner shall not, nor shall it cause or permit any of its Affiliates or any Third Party, to (and shall procure that its Affiliates (other than Excluded Partner Affiliates) do not and shall require in its agreements with its contractors that they do not) promote, market, recommend, sell or supply or otherwise Commercialize the Product or a Combination or Combined Dosage Therapy Product as a combination package in which the same is co-packaged with other pharmaceutical products, devices, pieces of equipment, components or substances for Commercialization.

(e) The rights granted under Article 3.1(a) do not include any right to Manufacture the Product and Partner and its Affiliates shall not Manufacture the Product nor purchase the Product from any Third Party except to the extent separately agreed in writing by Calliditas or as provided in Article 3.1(d).

(f) Partner shall not grant rights to any Third Party under the Licensed Intellectual Property to obtain or hold any Regulatory Approval with respect to the Product, unless legally required in a given country of the Partner Territory to enable Partner to engage distributors for Commercialization of Products in such particular country and in such event Partner shall procure that such Regulatory Approval is immediate assigned to Partner in the event of termination of the rights of such distributor and in any event upon termination of this Agreement.

3.5 Provision of Licensed Know-How.

(a) Promptly after the Effective Date, but in no event later than [***] thereafter, Calliditas will provide to Partner, in the format in which it is held by Calliditas or its Affiliates, access to or copies of Licensed Know-How in the possession of Calliditas or its Affiliates that is necessary for Partner to engage in the activities provided for and perform its obligations under this Agreement and the Supply Agreement, provided that no information relating to Manufacture of the Product shall be required to be provided pursuant to this Article 3.5.

(b) During the Term (but subject to Article 2.1), Calliditas shall provide to Partner full and prompt disclosure, but in no event less frequently than semi-annually or otherwise upon request of Partner for good cause shown, of any Licensed Know-How (excluding Licensed Know-How relating to Manufacture of the Product) that becomes Controlled by and into the possession of Calliditas or any of its Affiliates after the Effective Date and that is necessary for Partner to conduct its activities or exercise its rights as contemplated hereunder. Subject to Article 2.1, promptly after Calliditas or its Affiliates come into the possession and Control of Licensed Know-How required to be provided to Partner hereunder during the Term, Calliditas will provide the same to Partner, in the format in which it is held by Calliditas or its Affiliates.

(c) If reasonably necessary or useful for further permitted Development or Commercialization of the Product in the Partner Territory, and solely on request of Partner, Calliditas shall re-arrange, re-format, compile, correct, or otherwise undertake secondary review of any Licensed Know-How to be provided by Calliditas to Partner hereunder so that it is sufficiently understandable and useable for a reasonable Third Party in the position of Partner, whereby the FTE Cost of any such secondary review activities and all out-of-pocket costs shall be chargeable by Calliditas to Partner and shall be paid by Partner upon receipt of an invoice. Such secondary review activities and shall only be performed subject to the availability of necessary Calliditas personnel and only using methods and procedures used by Calliditas in the ordinary course of business. In the event that Partner identifies any additional Licensed Know-How (excluding Licensed Know-How relating to Manufacture of the Product) required to be provided by Calliditas and that has not been provided, Partner may provide notice to Calliditas and Calliditas shall, if Calliditas agrees that such Licensed Know-How is required to be provided by Calliditas, provide such Licensed Know-How to Partner within fifteen (15) Business Days.

(d) The transfer set forth in Article 3.5(a) shall occur in an orderly fashion and in a manner such that the value, usefulness and confidentiality of the transferred Licensed Know-How are preserved in all material respects. Calliditas shall provide such further reasonable consultation and assistance to Partner as reasonably requested by Partner in order to perfect the transfer set forth in Article 3.5(a). Calliditas shall provide such further reasonable consultation and assistance to Partner free of charge until such consultation and assistance provided by Calliditas exceeds a total amount of [***] hours of work. Any further consultation and assistance thereafter, shall be chargeable by Calliditas to Partner at the FTE Cost and shall be performed subject to the availability of necessary Calliditas personnel and only using methods and procedures used by Calliditas in the ordinary course of business.

(e) Partner shall, promptly after Partner or its Affiliates has come into the possession of the same, provide to Calliditas all data and information arising from Development activities in connection with the Product or Combination or Combined Dosage Therapy Product and all Know-How within the New Partner IP.

(f) Notwithstanding the provisions of this Agreement, Calliditas shall not be obliged to provide information relating to the process used for coating of beads used in the Product, nor other information related to the specifics of the Manufacturing of the Product, unless otherwise agreed by the Parties in the Supply Agreement or pursuant to Article 3.1(d).

3.6 Third Party In-Licenses. Calliditas shall be responsible for all payments associated with any agreements related to the Licensed Intellectual Property that exist as of the Effective Date, except as otherwise agreed by Partner in writing. In the event that, after the Effective Date, (a) Calliditas or its Affiliates acquire Control of Licensed Intellectual Property, or (b) an entity (other than an Acquirer) becomes an Affiliate of Calliditas, which entity Controls Licensed Intellectual Property; and, in either such event Calliditas or its Affiliate or such entity owes payments or is subject to other restrictions or obligations in respect of such Licensed Intellectual Property, Calliditas shall notify Partner of the existence of such restrictions or obligations. Partner shall have the right to decline a license under the applicable Licensed Intellectual Property or take such license, provided that if Partner elects to take such a license, Partner be obliged to enter into a separate agreement with Calliditas or its Affiliates sufficient to enable Calliditas and its Affiliates to comply with the applicable restrictions or obligations owed. Unless and until the Partner elects to take such a license and executes such separate agreement with Calliditas or its Affiliates, the relevant Licensed Intellectual Property shall be deemed to be excluded from the definitions of "Licensed Patents", "Licensed Know-How" and "Licensed Intellectual Property" for all purposes except this Article 3.6. Partner shall be responsible for all payments due to any third party to the extent triggered (in whole or in part) by the grant of such license to Partner or exercise by Partner of such license; provided that, with respect to Licensed Intellectual Property of which Calliditas or its Affiliates acquire Control by way of an in-license after the Effective Date, Partner shall only be responsible for such payments in respect of such Licensed Intellectual Property if:

(a) Calliditas was not in breach of Article 10.2(n) as at the Effective Date with specific reference to the relevant Licensed Intellectual Property; and

(b) where such in-license relates only to Licensed Intellectual Property necessary or useful in the Partner Territory:

(i) Calliditas has informed Partner of the need of obtaining such in-license promptly upon Calliditas' becoming aware of such need and, in any event, as soon as reasonably possible after (or preferably prior to) commencing negotiations for such in-license with such Third Party licensor;

(ii) prior to executing such license with the Third Party, Partner has not notified Calliditas that it wishes to obtain such necessary license from the Third Party directly (rather than in form of a sublicense from Calliditas); and

(iii) Partner has been given the opportunity to join the negotiations on such in-license together with Calliditas from commencement of substantive detailed negotiations onwards;

provided that the foregoing provisions of this Article 3.6(b) shall not apply where such in-license covers Patents or Know-How other than solely Patents and Know-How necessary or useful in the Partner Territory.

3.7 Trademarks.

(a) As of the Effective Date, Calliditas hereby agrees to transfer and assign, and to cause its Affiliates to transfer and assign, and hereby transfers and assigns to Partner all worldwide right, title, and interest in, to and under the Calliditas Trademarks, whether registered or not, and all related internet domain names and registrations, including those listed on Schedule 1. Partner herewith accepts such transfer and assignment. With regard to registration, maintenance and prosecution of the Calliditas Trademarks Article 7.9 shall apply. Notwithstanding the assignment of the Calliditas Trademarks or any other provision of this Agreement, Partner (and its Affiliates and contractors) may use the Calliditas Trademarks (or corresponding trademarks worldwide) only on or in relation to the permitted Manufacture and Commercialization of Products or Combination or Combined Dosage Therapy Products in the Territory for Commercialization in the Partner Territory or, subject to Article 3.4(b), for Commercialization in the Calliditas Territory and shall not use the same on or in relation to the manufacture or commercialization of any other products or outside the Partner Territory.

(b) Calliditas agrees to execute any and all further instruments, forms of assignment or other documents, and take such further actions, as Partner may reasonably request, in order to perfect the allocation of Calliditas Trademarks in accordance with Article 3.7(a) and to enable Partner to exercise its right to register, prosecute and maintain the Calliditas Trademarks as set forth in Article 7.9. Calliditas shall grant to Partner all necessary powers of attorney to enable Partner to act in the name and on behalf of Calliditas towards all competent trademark registries worldwide in order to effect the registration of transfer of ownership of the Calliditas Trademarks or to prosecute and maintain the Calliditas Trademarks prior to registration of transfer of ownership.

(c) Neither Party shall do, or omit to do, or permit to be done, any act that will or may weaken, damage or be detrimental to the Calliditas Trademarks or the reputation or goodwill associated with the Calliditas Trademarks, or that may invalidate or jeopardize any registration of Calliditas Trademarks (or corresponding trademarks worldwide), whereby the Parties acknowledge that the Calliditas Trademarks in the Calliditas Territory may be invalidated for lack of use by Partner.

(d) Calliditas shall neither use the Calliditas Trademarks (or a confusingly similar trademark) for Products or in connection with the Commercialization of the Products in the Calliditas Territory nor for products other than the Products nor as part of its company name, as special designation of its business or enterprise or otherwise as a sign to distinguish its business or as part of an Internet domain name. Calliditas has not granted and will not grant to any Third Party a right to use the Calliditas Trademarks for Products or Combination or Combined Dosage Therapy Products or in connection with the Commercialization of the Products or Combination or Combined Dosage Therapy Products in such other territories.

(e) The transfer and assignment of the Calliditas Trademark to Partner pursuant to this Article 3.7 shall not cause any obligation of Partner to exploit the Calliditas Trademark in the Partner Territory. Partner shall at any time during the Term be permitted to use its own alternative trademarks for the Commercialization of Products in the Partner Territory, subject to its diligence obligations. In the event that Partner elects to Commercialize the Product in the Partner Territory under a new, own trademark (instead of any of the Calliditas Trademarks), Partner shall notify Calliditas of such new trademark (name and design) no later than thirty (30) days prior to use of such own trademark.

3.8 Discussions on New Indications.

(a) [***].

(b) [***].

(c) [***].

3.9 Development of Combination or Combined Dosage Therapy Products or Improved Products

[***]:

(a) [***].

(b) [***].

(c) [***].

(d) [***].

(e) [***].

ARTICLE 4

MANAGEMENT

4.1 Joint Steering Committee. Within [***] days after the Effective Date, the Parties will establish a joint steering committee to oversee the Development and Commercialization of the Product in the Partner Territory and, solely if and to the extent relevant for Development or Commercialization of the Product in the Partner Territory, in the Calliditas Territory, and to monitor and provide overall strategic oversight of the activities under this Agreement (the "**JSC**").

(a) **Membership**. The JSC shall be composed of up to [***]members, with up to [***] members appointed by each Party. Promptly following the Effective Date (and no later than [***] thereafter), each Party shall appoint its initial representatives to the JSC. Each Party may replace its JSC representatives at any time upon written notice to the other Party. Calliditas will designate one of its representatives as the chairperson of the JSC. The chairperson shall be responsible for scheduling meetings, preparing and circulating an agenda in advance of each meeting (provided, that either Party may request to include a specific item on any such agenda), preparing and issuing minutes of each meeting within thirty (30) days thereafter, revising such minutes to reflect timely comments thereon, and overseeing the ratification of such revised minutes. The Parties shall also each appoint an alliance manager to serve as the primary point of contact for each Party under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall not be members of or have voting rights at the JSC, but shall be required to attend the meetings thereof.

(b) **Meetings**. The first meeting of the JSC shall occur upon its establishment, hence no later than [***] after the Effective Date. Until completion of the Ongoing Clinical Trial, the JSC shall meet at least on a monthly basis. The Parties shall endeavor to schedule monthly meetings of the JSC at [***] in advance. Thereafter, the JSC shall meet a minimum of [***] times per year. The Parties shall endeavor to schedule semiannual meetings of the JSC at least two (2) months in advance. At each meeting of the JSC, Partner shall provide the JSC with an update regarding the work performed by or on behalf of itself with respect to the Commercialization of the Product in the Partner Territory since the last meeting. Either Party may invite, at its cost, subject matter experts or other relevant personnel to attend any meeting of the JSC, provided that such participants are bound under written obligations of confidentiality and non-use no less protective of the Parties' Confidential Information than those set forth in this Agreement. The JSC may meet in person or by audio or video conference as its representatives may mutually agree.

(c) **Responsibilities**. The JSC may discuss, in particular but not limited to, the following matters:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***];

(vii) [***];

(viii) [***];

(ix) [***];

(x) [***];

(xi) [***]; and

(xii) [***].

4.2 Decision Making; Authority. Following the reasonable consideration of comments by each Party's representative members, the JSC shall make its decisions by consensus, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC and within the scope of its authority the representatives of the Parties on the JSC cannot reach consensus as to such matter, then the Parties shall refer such Dispute to the Applicable Senior Officers for attempted resolution by good faith negotiations within [***] after such referral is made. If the Applicable Senior Officers are unable to resolve the Dispute within the time allotted then (i) Calliditas shall have the final decision-making authority with respect to any matter related to Clinical Trials conducted by or on behalf of Calliditas; (ii) Partner shall have the final decision-making authority with respect to (x) any matter related to approved Clinical Trials conducted by or on behalf of Partner in the Partner Territory and (y) any matter related to Commercialization of the Product in the Partner Territory, without limitation of Partner's diligence obligations under this Agreement.

4.3 General Principles.

(a) The JSC have no authority beyond the specific responsibilities set forth in this Agreement with respect thereto. In particular, and without limiting the generality of the foregoing, the JSC may not amend or modify the terms or provisions of this Agreement.

(b) Each Party shall ensure that its representatives to the JSC have appropriate expertise and authority to serve as members of such committee. Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating. Each Party shall be responsible for all of its own expenses of participating in JSC meetings. Each Party shall use good faith and cooperative efforts to facilitate and assist the efforts of the JSC.

(c) The JSC shall continue to exist until the Parties mutually agree to dissolve it.

(d) Each Party undertakes that it shall provide copies of all material documents relating to the topics under the purview of the JSC to the Alliance Manager of the other Party as promptly as reasonably practicable following the generation or receipt thereof.

ARTICLE 5

COMMERCIALIZATION

5.1 Manufacture and Supply of Product. As of the Effective Date, the Parties have entered into a separate supply agreement (the "**Supply Agreement**"), which Supply Agreement provides for the entry into a related quality agreement (the "**Quality Agreement**") pursuant to which Calliditas (itself or through its Affiliates or contractors) will supply all of Partner's (and its Affiliates' and contractors') requirements of Product.

5.2 Overview of Commercialization. Subject to the terms and conditions of this Agreement, Partner shall be solely responsible for the Commercialization of the Product in the Field in the Partner Territory.

5.3 Commercialization Plan. As soon as reasonably feasible after the Effective Date, but in no event later [***] thereafter, Partner shall provide to Calliditas an initial commercialization plan which represents the preliminary projections of Partner regarding the Commercialization of the Product in the Partner Territory (the "**Commercialization Plan**"). No later than [***] after the Effective Date and at least twice per calendar year thereafter, Partner shall propose to the JSC changes, revisions and updates to the Commercialization Plan, provided that any material changes proposed by Partner and presented to the JSC shall be reasonable and based on a rationale provided in reasonable detail to the JSC when proposed, and the Parties shall discuss any such proposal in good faith, acting reasonably. The final determination as to what changes or revisions shall be made to the Commercialization Plan shall be made by Partner following discussion at the JSC and Partner shall provide a final copy of such updated plan to Calliditas. The JSC shall create a commercialization committee, which committee shall operate substantially in accordance with the terms of Article 4, to consider, discuss and provide input into the Commercialization of the Product in the Partner Territory.

5.4 Efforts.

(a) Partner shall:

(i) use Commercially Reasonable Efforts to:

(A) [***]; and

(B) [***].

Partner may decide based on the Commercially Reasonable Efforts to [***];

(ii) [***];

(iii) exercise its rights under this Agreement and perform its obligations under the Commercialization Plan in a professional manner, and in compliance with all material aspects of such Commercialization Plan and the requirements of Applicable Laws;

(iv) be solely responsible for all costs and expenses associated with its Commercialization of the Product in the Partner Territory; and

(v) [***].

(b) [***].

5.5 Reporting. Partner shall, at least once per Calendar Quarter from the Effective Date, provide to Calliditas a written report, in such form as may be reasonably required by Calliditas after consultation through the JSC, detailing:

(a) the status and progress of Partner's Development activities in each country of the Partner Territory;

(b) a summary of Partner's proposed Development activities in the next Calendar Quarter with respect to the Product in each country of the Partner Territory; and

(c) a description of Commercialization activities with reference to the Commercialization Plan for each country of the Partner Territory.

5.6 Booking of Sales and Handling Returns.

(a) As between the Parties, each Party shall be solely responsible for booking sales of the Product sold in its Territory. Each Party may warehouse the Product both inside and outside of such Party's Territory, provided that any sales with respect to such Product occur and are booked in such Party's Territory.

(b) As between the Parties, each Party shall be solely responsible for handling all returns of any Product sold in its Territory, as well as all aspects of Product order processing, invoicing and collection, distribution, inventory and receivables of Product sold in such Territory.

5.7 Ex-Territory Sales; Export Monitoring.

(a) **Ex-Territory Sales**. Subject to Applicable Laws, neither Party shall engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of such Product located outside of its Territory or accept orders for the Product from or sell the Product into such other Party's Territory for its own account, and, if a Party receives any order for the Product in the other Party's Territory, it shall refer such orders to the other Party, to the extent it is not prohibited from doing so under Applicable Laws.

(b) **Export Monitoring**. [***].

5.8 Non-Compete.

(a) [***].

(b) [***].

(c) [***].

ARTICLE 6

PAYMENTS

6.1 Upfront Payment. In consideration of the licenses and other rights granted hereunder, Partner shall pay to Calliditas a non-refundable, non-creditable and not subject to set-off payment in the amount of twenty million Euros (EUR 20,000,000) within thirty (30) days following the Effective Date subject to receipt of an invoice for the upfront payment from Calliditas.

6.2 Milestone Payments.

(a) **Development Milestone Payments**. In consideration of the licenses and other rights granted hereunder, Partner shall pay to Calliditas the non-refundable, non-creditable, and not subject to set-off milestone payments set forth below (each, together with the reimbursement milestone payment described in Article 6.2(b), a "**Development Milestone Payment**") upon the first achievement by or on behalf of Partner or its Affiliates of each of the corresponding events (each, together with the reimbursement milestone event described in Article 6.2(b), a "**Development Milestone Event**"). Partner shall notify Calliditas in writing promptly after achievement of the applicable Development Milestone Event and shall pay the corresponding Development Milestone Payment within forty-five (45) days after receipt of Calliditas' invoice therefore. Each of the milestone payments set forth in this Article 6.2(a) is payable only once upon the first achievement of such Development Milestone Event with the Product.

Development Milestone Event	**Development Milestone Payment**
Grant of Conditional Regulatory Approval and related maintenance of the Orphan Designation	[***]
Grant of Unconditional Regulatory Approval and related maintenance of Orphan Designation	[***]

(b) **Reimbursement Milestone Payment**. In consideration of the licenses and other rights granted hereunder, Partner shall pay to Calliditas a non-refundable, non-creditable and not subject to set-off payment in the amount of [***] within [***] after the Product obtains a final reimbursement amount (*Erstattungsbetrag*) based on price negotiations with the Federal Association of Statutory Health Insurance Funds (*Spitzenverband Bund der Krankenkassen*) according to section 130b of Volume V of the German Social Insurance Code (*Fünftes Buch Sozialgesetzbuch*) but no later than [***].

(c) **Sales Milestone Payments**. In consideration of the licenses and other rights granted hereunder, Partner shall pay to Calliditas the non-refundable, non-creditable, and not subject to set-off milestone payments set forth below (each, a "**Sales Milestone Payment**") upon the first (first time and one time) achievement by or on behalf of Partner or its Affiliates of each of the corresponding events with annual (not cumulative) Net Sales of a Product in the Partner Territory (each, a "**Sales Milestone Event**"). Partner shall notify Calliditas in writing promptly after achievement of the applicable Sales Milestone Event and shall pay the corresponding Sales Milestone Payment within [***]after receipt of Calliditas' invoice therefore. Each of the milestone payments set forth in this Article 6.2(c) is payable only once upon the first achievement of such Sales Milestone Event with annual (not cumulative) Net Sales of the Product in a given year:

Sales Milestone Event	**Sales Milestone Payment**
Annual Net Sales for the Product in the Partner Territory reaches or exceeds [***]	[***]
Annual Net Sales for the Product in the Partner Territory reaches or exceeds [***]	[***]
Annual Net Sales for the Product in the Partner Territory reaches or exceeds [***]	[***]
Annual Net Sales for the Product in the Partner Territory reaches or exceeds [***]	[***]

(d) Until Partner has made all of the payments set forth in Article 6.2, Partner shall include as part of its royalty report pursuant to Article 6.5(f) following the end of each Calendar Year an affirmative statement for each threshold Net Sales amount set forth in Article 6.2 that the aggregate Net Sales of Product in the Partner Territory for the previous Calendar Year did or did not exceed such threshold.

6.3 Royalties. During the Royalty Term, Partner shall pay non-refundable, non-creditable royalty payments to Calliditas with respect to the Net Sales of the Product at the following rate, as such rate may be adjusted pursuant to Article 6.5 ("**Royalty Rate**"):

Net Sales	**Royalty Rates**
Where annual Net Sales for the Product in the Partner Territory fall below or reach [***]	[***]of Net Sales
Where annual Net Sales for the Product in the Partner Territory exceed [***]	[***]of Net Sales

6.4 Royalty Term. Royalties payable under Article 6.3 shall be payable on a country-by-country basis during the period beginning on the date of the First Commercial Sale of the Product in such country and ending on the latest of (a) the last to expire Valid Claim of the Licensed Patents (including Patents within the New Joint IP, unless otherwise agreed by the Parties) Covering the Product in such country, (b) the expiration of the last Regulatory Exclusivity Period applicable to such Product in such country, and (c) [***] of the First Commercial Sale after Regulatory Approval of such Product in such country; but in any event no later than upon [***] of the First Commercial Sale of a Product anywhere in the Partner Territory (not necessarily in the particular country) (the "**Royalty Term**").

6.5 Royalty Adjustments. The royalty payments due by Partner to Calliditas under this Agreement shall be subject to the following cumulative royalty adjustments:

(a) **Royalty Reduction upon [***] for the Product**. During the Royalty Term and on a country-by-country basis, the Royalty Rate which would otherwise be due in respect of the Net Sales of a Product pursuant to Article 6.3 shall be reduced by [***] if [***]. For example, if the Royalty Rate is [***] of Net Sales at the time of this reduction, it shall be reduced by [***] to a Royalty Rate of [***].

(b) **Royalty Reduction upon Expiry of Regulatory Exclusivity Period**. During the Royalty Term and on a country-by-country basis, the Royalty Rate which would otherwise be due in respect of the Net Sales of a Product pursuant to Article 6.3 shall be reduced by [***]upon expiry of the Regulatory Exclusivity Period for such Product in such country, provided that such expiration is not due directly to any breach of this Agreement by or on behalf of Partner or its Affiliates. For example, if the Royalty Rate is [***] of Net Sales at the time of this reduction, it shall be reduced by [***] to a Royalty Rate of [***]; if the Royalty Rate is (already reduced to) [***] of Net Sales at the time of this reduction, it shall be reduced by [***] to a Royalty Rate of [***]

(c) **Generic Version Entry**. During the Royalty Term and on a country-by-country basis, the Royalty Rate which would otherwise be due in respect of the Net Sales of a Product pursuant to Article 6.3 shall be reduced by [***]beginning with the royalty payment for the first Calendar Quarter commencing after unit sales of Generic Versions in such country exceed [***] of total unit sales of the combined unit sales of Generic Versions and the Product in two consecutive Calendar Quarters (as reasonably determined by Partner on the basis of unit sales data from IQVIA or another source of comparable reputation), provided however, that the Person holding Regulatory Approval for such Generic Version (the marketing authorization holder) in such country is not Partner or its Affiliate or any distributor of them in connection with the Commercialization under this Agreement.

(d) **Royalty Stacking**. If, during the Royalty Term, Partner is required to make any payments (including any upfront payments, milestone payments or royalties) to a Third Party in consideration (including as a result of settlement or dispute resolution) for any Patent, Know-How or other intellectual property right (excluding trademarks or tradenames) that, in the reasonable discretion of Partner, is necessary for Partner to Commercialize the Product in the Partner Territory in the Field, Partner may deduct from any royalty due on the Net Sales of such Product under Article 6.3 [***]of any payments due by Partner to the Third Party licensor for such license.

(e) **Minimum Royalties and Offsets**. In no event shall any royalty due under Article 6.3 be reduced by more than [***] of the amount that would otherwise be due after taking into account all adjustments and reductions applicable to such royalty pursuant to this Agreement ("**Minimum Royalties**"). Any royalty adjustment amounts in a country that are not applied to reduce a royalty payment in a reporting period in order to maintain the Minimum Royalties may be carried over by Partner and be used to offset royalty payments due in any subsequent reporting period for the same country.

(f) **Royalty Reports.** For as long as royalties or other payments are due under this Article 6, Partner shall provide Calliditas with royalty reports at the end of each calendar month. Partner shall provide to Calliditas, within [***] after the end of the calendar month (i) on a country-by-country basis, the amount of gross sales invoiced by Partner or its Affiliates for the sale of such Product in such month, deductions therefrom and royalties owed thereon; and (ii) the Net Sales in respect of such month and the annual Net Sales in respect of such Calendar Year. Royalty payments for each calendar month will be due at the same time as such reports for such month, subject to receipt of an invoice for the royalties from Calliditas.

(g) **True-up**. Where the royalty report in respect of a given calendar month reports that Net Sales in respect of such Calendar Year exceed [***], the royalty payment pursuant to Article 6.5(f) made at the time of such report shall include the additional royalty due at the higher rate in respect of Net Sales the subject of previous royalty reports in respect of such Calendar Year.

6.6 Payment Method. All payments due under this Agreement to Calliditas shall be made by bank wire transfer in immediately available funds to an account designated by Calliditas.

6.7 Other Amounts Payable. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified in this Agreement, the applicable Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed and the owing Party will pay any undisputed amounts within [***] of receipt of the invoice, and any disputed amounts owed by a Party will be paid [***] of resolution of the dispute.

6.8 Taxes.

(a) Notwithstanding anything else in this Article 6.8, each Party shall solely bear and pay all Taxes imposed on such Party's net income or gain (in each case, however denominated) arising directly or indirectly from the activities of the Parties under this Agreement. All payments due under this Agreement are exclusive of any VAT. In case that payments to be made hereunder are subject to VAT the paying Party shall pay to the receiving Party an amount equal to such VAT, in addition to such payment and at the time when such payment is due. The receiving Party shall reasonably promptly deliver, or shall procure that its relevant Affiliate shall reasonably promptly deliver, to the paying Party a VAT invoice in respect thereof, if and to the extent required or permitted by Applicable Law.

(b) Payments made to Calliditas hereunder shall be made in the full amounts set forth herein, except for any withholding taxes required by Applicable Law. If Partner is required pursuant to Applicable Law to withhold any amounts in respect of Taxes from payments made to Calliditas hereunder, Partner shall (i) deduct or withhold such Taxes from the payment made to Calliditas, (ii) timely pay such Taxes to the proper taxing authority, and (iii) send proof of payment to Calliditas within thirty (30) days following such payment. Accordingly, Partner shall not be obliged to "gross-up" any payments due to such withholding or deductions. Each Party shall comply with (or provide the other Party with) any certification, identification or other reporting requirements that may be reasonably necessary in order for Partner to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding Taxes or similar obligations resulting from payments made under this Agreement.

6.9 Interest. If either Party fails to make any payment due under this Agreement by the date upon which such payment is due (and such payment is not subject to a good faith dispute with the full undisputed portion having been paid), then interest of [***] above the base interest rate (according to sec. 247 German Civil Code (BGB)) p.a. shall accrue, or interest at the maximum rate permitted by Applicable Laws, whichever is the lower, and such interest shall be paid when such payment is made.

6.10 Currency Exchange. All amounts referred to in this Agreement are expressed in, and all payments to Calliditas or to Partner, as applicable, hereunder will be payable in, Euros. Sales in the Partner Territory, for purposes of determining the Net Sales amount shall be calculated using the exchange rate published by the European Central Bank under (https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/index.en.html) or, if not available, as otherwise mutually agreed in writing by the Parties.

6.11 Records.

(a) **Retention**. Partner shall keep, and shall cause its Affiliates to keep, (i) for at least five (5) years following the end of the Calendar Year to which they pertain adequate books and records of accounting for the purpose of calculating all royalties and other amounts payable to Calliditas under this Agreement, and (ii) for at least [***] following the end of the Calendar Year to which they pertain, other books and records documenting Partner's satisfaction of its obligations under Article 5.4. Such record keeping obligation shall survive any expiration or termination of this Agreement for the time provided herein.

(b) **Access to Records and Audit**. Subject to the other terms of this Article 6.11, Calliditas may audit the records referred to in Article 6.11(a). Such audit shall be conducted (i) after at least [***] written notice from Calliditas, at the facility(ies) where the applicable records are maintained and (ii) no more frequently than once in any Calendar Year. The audit shall be conducted by a nationally recognized accounting firm selected by Calliditas and to whom Partner has no reasonable objections. The auditor will execute a written confidentiality agreement with Partner that is substantially similar to the confidentiality provisions of Article 8 and limits the disclosure and use of information obtained from such audit to authorized representatives of the Parties and the purposes under this Article 6.11. The auditor will send a copy of their report to both Parties at the same time. In any event the auditor shall only share with Calliditas the findings and not the underlying data. Calliditas shall be responsible for expenses for the audit, except that Partner shall reimburse Calliditas for the cost of such audit if such audit reveals that payments made by Partner are less than [***] of the amount actually owed for the period of the audit.

(c) **Underpayment**. If, as a result of any audit pursuant to Article 6.11(b), it is shown that the payments to Calliditas were less than the amount that should have been paid pursuant to this Agreement, then Partner shall, within [***] after Calliditas' demand therefor, pay Calliditas the amount of such shortfall, increased by interest calculated as provided in Article 6.9.

ARTICLE 7

INTELLECTUAL PROPERTY

7.1 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license or other right (whether by implication, estoppel or otherwise) in or to any Know-How, Patents or other intellectual property rights of the other Party or any of such other Party's Affiliates, including tangible or intangible items owned, controlled or developed by the other Party or any of such other Party's Affiliates, or provided by the other Party or any of its Affiliates to the receiving Party or any of its Affiliates at any time, pursuant to this Agreement. As between the Parties, Calliditas is and will remain be the sole and exclusive owner (or, as applicable, co-owner) of and retains all right, title and interest in and to all Licensed Patents and Licensed Know-How.

7.2 Determination of Inventorship. Inventorship for inventions and discoveries first made during the course of the performance of activities under this Agreement will be determined in accordance with the applicable laws for determining inventorship.

7.3 Ownership.

(a) **New Calliditas IP**. As between the Parties, Calliditas will solely and exclusively own all right, title and interest in and to all Improvements (and Patents claiming inventions therein) conceived, discovered, developed, reduced to practice or otherwise made solely (as between the Parties) by or on behalf of one or more of Calliditas, its Affiliates and licensees (other than Partner or its Affiliates) (the "**New Calliditas IP**") and all confidential information incorporated in such New Calliditas IP shall be deemed Confidential Information of Calliditas.

(b) **New Partner IP**. As between the Parties, Partner will solely and exclusively own all right, title and interest in and to all Improvements (and Patents claiming inventions therein) conceived, discovered, developed, reduced to practice or otherwise made, solely (as between the Parties) by or on behalf of one or more of Partner and its Affiliates and contractors (the "**New Partner IP**") and all confidential information incorporated in such New Partner IP shall be deemed Confidential Information of Partner.

(c) **New Joint IP**.

(i) As between the Parties, both Parties will jointly own, all right, title and interest in and to all Improvements (and Patents claiming inventions therein), conceived, discovered, developed, reduced to practice or otherwise made, jointly by or on behalf of both of the Parties (the "**New Joint IP**"). All within the New Joint IP shall be deemed to be the Confidential Information of both Parties.

(ii) Unless otherwise agreed by the Parties pursuant to Article 3.9 with respect to joint Development projects, each Party shall notify the JSC about any New Joint IP upon such Party becoming aware thereof. Promptly upon JSC's notification about New Joint IP, the JSC shall determine whether or not such New Joint IP shall be kept confidential or whether any Patents claiming inventions in such New Joint IP shall be filed, prosecuted or maintained in the Territory (in the name of both Parties or, if ownership in New Joint IP is allocated to either of the Parties alone, in the name of such Party). If ownership in New Joint IP is allocated to either of the Parties alone, such New Joint IP shall be deemed to become New Calliditas IP or New Partner IP as applicable.

(iii) In case that the JSC does not allocate ownership in New Joint IP to either of the Parties, the JSC shall determine the rights and responsibilities for filing, prosecution and maintenance of the Patents within New Joint IP and in such case the Parties shall bear the costs jointly in the proportions determined by the JSC. Neither Party may file a Patent claiming New Joint IP without the prior consent of the other Party through the JSC.

7.4 Patent Prosecution and Maintenance.

(a) As between the Parties, Calliditas will have (i) the exclusive right and the obligation (provided that Calliditas may be released from such obligation pursuant to Article 7.4(b)), at its cost, to file, prosecute and maintain all Licensed Patents listed in Schedule 3 as at the Effective Date in the Major Market Countries in the Partner Territory; and (ii) the exclusive right (but not the obligation), at its cost, to file, prosecute and maintain all Patents within the New Calliditas IP, and Licensed Patents in any other country. In respect of the Licensed Patents listed in Schedule 3 as at the Effective Date in the Major Market Countries, Calliditas will provide to Partner copies of all draft filings and material documents filed with, sent to or received from the relevant national patent offices or other Governmental Authorities in the course of filing, prosecuting and maintaining such Patents, in the case of such filings and such filed or sent documents, where reasonably possible in sufficient time to provide Partner with a reasonable opportunity to comment thereon prior to their submission to the relevant national patent office or other Governmental Authority, and will consider in good faith (but, for clarity, will have no obligation to incorporate) such comments where timely received. With regard to all other Patents for which Calliditas has the first right to file, prosecute and maintain, Calliditas will provide to Partner (i) once a year in the second Calendar Quarter, a description in reasonable detail of its patent prosecution and maintenance strategy and activities, and (ii) an update on then-current activities in the fourth Calendar Quarter of each year (or promptly in the event of any significant unanticipated development).

(b) Should Calliditas decide that it is no longer interested in maintaining or prosecuting a Patent within the Licensed Patents, which Patent relates to the Product, in any country of the Partner Territory, it will promptly advise Partner in writing, and Partner will have the right, but not the obligation, to assume such prosecution and maintenance in the Partner Territory at its sole cost and expense. Calliditas shall be released from its obligations under Article 7.4(a) with respect to such Patent twenty (20) Business Days after the date of such notice. If Partner advises Calliditas, within twenty (20) Business Days of Partner's receipt of such notice from Calliditas, that Partner desires to assume the prosecution or maintenance of the applicable Patent at Partner's expense, then Calliditas will not so abandon or fail to prosecute or maintain such Patent and shall permit Partner to assume such responsibility. Where Partner decides to make such assumption, the Patent for which Partner assumes the responsibility to file, prosecute and maintain (i) will continue to be included in the definition of "Licensed Intellectual Property" for the purpose of the license granted under this Agreement, but (ii) will no longer be included in the definition of "Valid Claim" for the purpose of determination of the Royalty Term under this Agreement.

(c) As between the Parties, Partner will have the exclusive right (but not the obligation), at its cost, to file, prosecute and maintain all Patents within the New Partner IP. Partner will provide to Calliditas copies of all draft filings and material documents filed with, sent to or received from the relevant national patent offices or other Governmental Authorities in the course of filing, prosecuting and maintaining the Patents within the New Partner IP (the "**Partner Controlled Patents**"), in the case of such filings and such filed or sent documents, in sufficient time to provide Calliditas with a reasonable opportunity to comment thereon prior to their submission to the relevant national patent office or other Governmental Authority, and will consider in good faith (but, for clarity, will have no obligation to incorporate) such comments. Should Partner decide that it is not interested in filing or is no longer interested in maintaining or prosecuting a Patent within or claiming New Partner IP which relates solely and exclusively to the Product, it will promptly advise Calliditas in writing, and Calliditas will have the right, but not the obligation to assume, such filing, prosecution and maintenance at its sole cost and expense. If Calliditas advises Partner, within twenty (20) Business Days of Calliditas' receipt of such notice from Partner, that Calliditas desires to assume the prosecution or maintenance of the applicable Patent at Calliditas' expense, then Partner will not abandon or fail to prosecute or maintain such Patent and shall permit Calliditas to assume such responsibility. Where Calliditas decides to make such assumption, Partner will promptly assign all of its rights, title and interests in and to the applicable Patent to Calliditas, and such assigned Patent will, from and after the date of such assignment, (i) be deemed to be included in the definition of "Licensed Intellectual Property" for the purpose of the license granted under this Agreement, but (ii) will not be included in the definition of "Valid Claim" for the purpose of determination of the Royalty Term under this Agreement.

7.5 Infringement by Third Parties.

(a) **Notice**. Each Party will promptly report in writing to the other Party's Alliance Manager any Competitive Infringement of which such Party becomes aware.

(b) **Right to Bring Suit**.

(i) Calliditas will have the first right (but not the obligation), at its sole expense, and, as required to bring or maintain such suit (if legally required in a given country in the name of Partner), using counsel of Calliditas' choosing, to bring and control any action or proceeding to abate any alleged or threatened Competitive Infringement in the Partner Territory by enforcing any Licensed Patent in the Partner Territory. If Calliditas does not bring and continue pursuing an action or proceeding against, or otherwise take steps to abate a Competitive Infringement in the Partner Territory within [***] following the notice of such an alleged Competitive Infringement, then Partner will have the right to bring and control an action to enforce any Licensed Patent in the Partner Territory to abate such Competitive Infringement at its sole expense and by counsel of its own choice provided that in the event of a counterclaim alleging the invalidity or unenforceability of any Licensed Patent, as between the Parties, Calliditas shall have the right (without any obligation) to defend any such action.

(ii) Calliditas will have the sole right (but not the obligation), at its sole expense, using counsel of Calliditas' choosing to bring and control any action or proceeding to abate any alleged or threatened Competitive Infringement in the Calliditas Territory.

(c) **Cooperation; Settlement**. For any action or proceeding brought by a Party under Article 7.5(b)(i) (the "**Initiating Party**"), regardless of which Party brings such action or proceeding, the other Party (the "**Non-Initiating Party**") shall cooperate reasonably in any such effort, all at the Initiating Party's expense, and the Parties shall reasonably cooperate to address new facts or circumstances that come to light during the course of any such action or proceeding that may affect the need for one Party or the other to participate in such action. The Non-Initiating Party agrees to join or be joined as a party to such action, at the Initiating Party's expense, if needed for the Initiating Party to bring or continue an infringement action hereunder. The Non-Initiating Party shall, at its own expense and with its own counsel, have the right to observe and provide comments with respect to any action brought by the Initiating Party under this Article 7.5 (which comments the Initiating Party shall consider in good faith but be under no obligation to incorporate). Neither Party may settle an action or proceeding brought under this Article 7.5 in a manner that, or knowingly take any other action in the course thereof that, (i) imposes any monetary restriction or obligation on or admit fault of the other Party or (ii) adversely affects the value, scope or validity of, or otherwise adversely affects the other Party's rights under this Agreement to as applicable, the Licensed Intellectual Property (including, for Calliditas, the exploitation of such Patents in the Calliditas Territory), in each case, without the written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(d) **Recoveries**. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery realized by Calliditas or Partner as a result of any litigation under Article 7.5(b)(i) (whether by judgement, award or settlement), shall be distributed to the Parties as follows: [***] .

7.6 Defense of Licensed Patents. Each Party shall notify the other Party in the event that such Party becomes aware of any threat or proceeding challenging the validity of the Licensed Patents and in such case Calliditas shall have the first right (but not the obligation), at its sole expense, to control the defense of the Licensed Patent against such challenges. If Calliditas does not take control of the defense of the Licensed Patent, within (x) [***] following the notice of challenge of the validity of the Licensed Patent or (y) any shorter period legally applicable to defend such challenge, then Partner will have the right to control such defense at its sole expense and by counsel of its own choice. With regard to cooperation, settlement and recoveries, Article 7.5(c) and (d) shall apply accordingly.

7.7 Defense of Alleged Infringement of Third Party Rights. Subject to Article 11, in the event that any Third Party claims intellectual property infringement against the Partner or any of its Affiliates as a result of the use of the Licensed Intellectual Property in the Partner Territory, the use of the New Partner IP, the Commercialization of Products in the Partner Territory, Partner shall have the exclusive right and responsibility to defend any such claim brought against the Partner or its Affiliates. Partner shall keep Calliditas regularly informed regarding the strategy and content of its defense and Calliditas may observe and provide comments with respect to the same, which comments shall be considered by Partner in good faith. Partner shall be free to enter into any settlement or other voluntary disposition of such claim, provided that any such settlement or other voluntary disposition that limits the scope, validity or enforceability of the Licensed Intellectual Property or restricts the Development, Manufacturing, or Commercialization of the Products in the Calliditas Territory, or admits fault or wrongdoing on the part of the Calliditas or its Affiliates or partners in the Calliditas Territory, must first be approved in writing by Calliditas (such approval not to be unreasonably withheld, delayed or conditioned). Calliditas shall be deemed to have given its approval to any such settlement or other voluntary disposition if it fails to give notice to Partner that it either (a) approves or (b) rejects (giving reasonable details of the grounds relied on by Calliditas to substantiate its decision to reject) such settlement or other voluntary disposition within [***] of receipt of a request from Partner for its approval (such initial request to provide a copy of the proposed settlement or disposition and all other information which Calliditas may reasonably require to consider the matter at hand).

7.8 Patent Extensions. With respect to any election for patent term extension, supplemental protection certificate or any of their equivalents with respect to the Licensed Patents or Patents within New Calliditas IP, Calliditas will have the sole and exclusive right (but not the obligation) to seek such extensions in the Partner Territory at Calliditas' sole cost and expense. Upon the written request by Calliditas, Partner will reasonably cooperate with the implementation of such decisions. Calliditas shall consider reasonably and in good faith requests from Partner with respect to such extensions in the Partner Territory. If Calliditas confirms in writing to Partner that it does not intend to seek any such extensions in the Partner Territory, Partner may seek such extensions in the Partner Territory at Partner's sole cost, in Calliditas' name.

7.9 Trademarks.

(a) Upon the transfer and assignment of Calliditas Trademarks pursuant to Article 3.7, Partner shall have:

(i) the sole right and the obligation, at Partner's expense, to undertake Commercially Reasonable Efforts to prosecute and maintain the Calliditas Trademarks in all territories covered by the Calliditas Trademarks as at the Effective Date;

(ii) the sole right (but not the obligation) to register, maintain and prosecute trademarks corresponding to the Calliditas Trademarks in other territories in the Partner Territory and in the Calliditas Territory at its sole cost and expense.

(b) Calliditas shall notify Partner without undue delay if it becomes aware of any infringement of the Calliditas Trademarks in the Partner Territory or the Calliditas Territory, in particular, if Calliditas becomes aware that a Third Party registers or uses a designation as a trademark which is confusingly similar to the Calliditas Trademarks. Partner shall have the sole right, but not the obligation, to defend the infringement at its sole cost and expense.

(c) If the existence of the Calliditas Trademarks in the Partner Territory or the Calliditas Territory is challenged by Third Parties by way of cancellation actions or requests for cancellation or otherwise, or if claims are asserted against Partner by a Third Party for use of the Calliditas Trademarks, the defense against these shall be exclusively reserved to Partner, unless Calliditas is obliged by Applicable Laws to participate in the dispute as a party to the proceeding. In any event, Calliditas shall use its Commercially Reasonable Efforts to assist Partner. Any costs incurring from such dispute, including Calliditas' costs in providing such assistance, shall be borne by Partner.

ARTICLE 8

CONFIDENTIALITY AND DATA PROTECTION

8.1 Definition of Confidential Information. During the Term, either Party (the "**Disclosing Party**") or its Affiliates may from time to time furnish the other Party (the "**Receiving Party**") or its Affiliates with scientific, technical, trade or business information or materials which are treated by the Disclosing Party as confidential or proprietary, including, without limitation, information and materials related to, the Product, processes, formulae, procedures, tests, equipment, data, batch records, reports, know-how, sources of supply, patent positioning, relationships with consultants and employees, business plans and business developments, and information concerning the existence, scope or activities of any research, design, development, Manufacturing, marketing or other projects. All such information shall be referred to herein as "**Confidential Information**". "**Calliditas Confidential Information**" means any and all Confidential Information for which Calliditas is the Disclosing Party and Partner the Receiving Party hereunder or that is otherwise attributed to Calliditas pursuant to this Agreement. "**Partner Confidential Information**" means any and all Confidential Information for which Partner is the Disclosing Party and Calliditas the Receiving Party hereunder or that is otherwise attributed to Partner pursuant to this Agreement.

8.2 Confidentiality and Duration of Confidentiality Obligations. Except (a) to the extent otherwise expressly authorized by this Agreement, or (b) as otherwise agreed in writing by the Parties, the Receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose any Confidential Information of the Disclosing Party. Unless otherwise provided for in this Agreement, the Parties' obligations of confidentiality, non-disclosure and non-use set forth in this Article 8 shall survive any expiry or termination of this Agreement for a period of ten (10) years after the effective date of a termination or date of expiry.

8.3 Exclusions. Notwithstanding anything herein to the contrary, the obligations of confidentiality and non-use under this Article 8 applicable to Confidential Information hereunder shall not apply to information that:

(a) at the time of disclosure, is known publicly or thereafter becomes known publicly through no fault of the Receiving Party or anyone to whom the Receiving Party has disclosed the Disclosing Party's Confidential Information;

(b) is disclosed to the Receiving Party or its Representatives on a non-confidential basis by a Third Party that is not subject to any confidentiality obligations to the Disclosing Party with respect to such information;

(c) was developed by the Receiving Party or its Representatives without use or knowledge of the Disclosing Party's Confidential Information, as shown by the Receiving Party's or its Representatives' prior written records;

(d) was already known to the Receiving Party or its Representatives on a non-confidential basis before receipt from the Disclosing Party, as shown by the Receiving Party's prior written records (provided that this shall not relieve Partner of its obligation with respect to Know-How within the New Partner IP); or

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(e) is released with the prior written consent of the Disclosing Party (subject to the terms and conditions, if any, set out in the applicable consent).

8.4 Permitted Disclosures. Notwithstanding the foregoing, each Receiving Party may disclose the Disclosing Party's Confidential Information:

(a) to the Receiving Party's or its Affiliates' employees, directors, consultants, financial and other advisors, agents, and contractors (but not, as concerns Partner, to Excluded Partner Affiliates except to selected personnel of Excluded Partner Affiliates in course of applicable governance and steering proceedings (e.g. under a domination agreement)) and in the case of Calliditas not to its actual and potential licensees (except where required to specify the scope of intellectual property rights Controlled by Calliditas under any such actual and potential license agreement) ("**Representatives**"), who, in each case, are bound by obligations relating to confidentiality at least as restrictive of those contained herein and who have a need to know such information in connection with the Receiving Party's performance of its obligations or practice of its licenses and other rights under this Agreement; provided, however, that each Party will remain responsible for any act or omission by its Representatives which would, if effected by a Party, constitute a breach of this Article 8,

(b) to Regulatory Authorities in connection with any Regulatory Submissions required for development or commercialization of Product or compliance with Regulatory Requirements (i) in the case of Partner as Receiving Party, in the Partner Territory only; and (ii) in the case of Calliditas as Receiving Party, in the Calliditas Territory only,

(c) to any actual or potential acquirer, merger partner, underwriter, investor, lender or other provider of financing, in each case in respect of the Receiving Party, and the employees, directors, agents, consultants and advisors of any such Third Party, provided that they have entered into legally binding written obligations relating to confidentiality at least as restrictive of those contained herein (but of duration customary in confidentiality agreements entered into for a similar purpose);

(d) in the case of Partner to its subcontractors (including analytic laboratories or distributors) engaged in the permitted Development, Manufacture or Commercialization of the Products in the Field in the Partner Territory, who, in each case, are bound by obligations relating to confidentiality at least as restrictive of those contained herein and who have a need to know such information in connection with the Partner's performance of its obligations or practice of its licenses and other rights under this Agreement; provided, however, that Partner will remain responsible for any act or omission by its subcontractors which would, if effected by Partner, constitute a breach of this Article 8; or

(e) pursuant to Articles 8.5 and 8.6 or upon prior written approval of the other Party.

8.5 Terms of Agreement. The Parties agree that the terms of this Agreement will be considered Confidential Information of both Parties. Subject to Articles 8.4 and 8.6 and except as set forth below, no Party shall, without the prior written consent of the other Party, disclose in any manner to any Third Party the terms of this Agreement, except for terms or subject matter which has been the subject of prior public disclosure or has been mutually approved by the Parties in writing for such disclosure. Each Party acknowledges that the other Party may be legally required to file this Agreement as an exhibit to its filings with an applicable securities regulator (for example, as may pertain to the United States Securities and Exchange Commission or Swedish Finansinspektionen), subject to customary and legally permitted redaction of Confidential Information of the other Party. In addition: (a) either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, pursuant to Applicable Laws and stock exchange rules (e.g., the rules of the United States Securities and Exchange Commission, Nasdaq Stockholm, or any other stock exchange on which securities issued by either Party may be listed); provided that, such Party shall, to the extent permitted and if feasible in light of applicable time constraints, provide the other Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement) sufficiently in advance (to the extent possible) of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text (including redacted versions of this Agreement), (b) either Party shall have the further right to disclose the terms of this Agreement under a confidentiality obligation no less protective than those set forth in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose), to any actual or potential sublicensee, strategic partner, collaborator, acquirer, merger partner, underwriter, investor, lender or other provider of financing, and the employees, directors, agents, consultants and advisors of any such Third Party, and (c) each Party shall have the right to disclose information regarding the Development or Commercialization status of the Product in their respective Territory to the extent such disclosure is required by Applicable Laws.

8.6 Mandatory Disclosure.

(a) **Notification and Consultation**. In the event that the Receiving Party is required by applicable statute or regulation or by court order or judicial or administrative process to disclose any part of the Disclosing Party's Confidential Information (including material terms or conditions of this Agreement), the Receiving Party shall to the extent permitted (i) promptly notify the Disclosing Party (if feasible in light of applicable time constraints) of each such requirement and identify the documents so required thereby, so that the Disclosing Party may seek or request the Receiving Party to seek an appropriate protective order, confidential treatment or other remedy or waive compliance by the Receiving Party with the provisions of this Agreement and (ii) if feasible in light of applicable time constraints, consult with the Disclosing Party on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

(b) **Limited Disclosure**. If, in the absence of such a protective order, confidential treatment request, other remedy or waiver by the Disclosing Party regarding a disclosure pursuant to Article 8.6(a), the Receiving Party is nonetheless required to disclose any part of the Disclosing Party's Confidential Information or any material terms or conditions of this Agreement, the Receiving Party may disclose such Confidential Information or material terms or conditions without liability under this Agreement, except that the Receiving Party shall furnish only that portion of the Confidential Information or material terms or conditions that is legally required.

8.7 Data Protection.

(a) The Parties acknowledge and agree to comply with all applicable data protection rules and legislation, including the GDPR and the regulations on the doctor-patient confidentiality.

(b) Each Party agrees that personal data will only be processed as far as is necessary for the purposes of this Agreement, and only on a lawful basis as set forth in Articles 6 and Article 9 GDPR. To the extent that the processing and use of either Party's data, in particular health data, requires the patients' prior consent, the respective Party will be responsible to obtain such consent.

(c) Should any processing within the context of this Agreement be considered a processing under joint control pursuant to Article 26 GDPR, the Parties shall enter into a separate joint control agreement according to Article 26 GDPR.

(d) Insofar as pursuant and in connection with this Agreement the Parties transfer personal data to their Affiliates or to Third Parties, the Parties shall ensure that, by taking all appropriate measures, they comply with the applicable data protection and data secrecy laws. In particular, each Party agrees that it will process personal data outside of the EEA only if and to the extent in compliance with Articles 44 et seqq. GDPR. To ensure that the rights of the data subjects under this Agreement are not compromised when personal data are processed outside the EEA, the Parties agree to enter into standard contractual clauses or any other required data protection agreement. In doing so, the Parties also consider the Schrems II decision of the European Court of Justice according to which, although standard contractual clauses are still generally considered sufficient to protect personal data of EEA data subjects in compliance with the GDPR, a case-by-case assessment of the data protection standards provided in the destination jurisdiction is required.

ARTICLE 9

PUBLIC ANNOUNCEMENTS; USE OF NAMES

9.1 Public Announcements. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of each Party's respective press release attached hereto as **Schedule 4**, and the Parties will cooperate in the release of such press releases promptly after the Effective Date (and neither Party shall make any other statement to the public regarding the execution or any other aspect of the subject matter of this Agreement, except to the extent expressly permitted under this Agreement, including without limitation, pursuant to Article 8.5). Either Party may use the text of a statement previously approved by the other Party in subsequent public announcements.

9.2 Use of Names. Neither Party shall make use of the name of the other Party or any of its Affiliates in any advertising or promotional material, or otherwise, without the prior written consent of such other Party, except as permitted pursuant to Article 9.1 or Article 8. Notwithstanding the foregoing, either Party may use the name of the other Party or its Affiliates in the context of mentioning the existence of this Agreement in advertising or promotional materials or other materials required to be filed in accordance with applicable securities laws, or as required by any Governmental Authority or Regulatory Authority, including in conjunction with the Commercialization of the Product.

9.3 Publications. Each Party shall use Commercially Reasonable Efforts to provide to the other Party drafts of publications regarding the Product sufficiently in advance of their submission to provide a reasonable opportunity for comment and discussion between the Parties, and for the removal of any Confidential Information of such other Party, and such Party shall consider in good faith any such comments; provided, however, that, except as otherwise provided in this Agreement, such Party shall not be obligated to incorporate any such comments into such publications. Partner shall include a customary acknowledgment of Calliditas as the licensor of the Product in any publications by or on behalf of Partner. Nothing in this Article 9.3 grants to either Party any right to publish the Confidential Information of the other Party (even if the other Party has had the opportunity to review the proposed publication) and the provisions of this Article 9.3 are without prejudice to the provisions of Article 8.

ARTICLE 10

REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Mutual Representations and Warranties of Calliditas and Partner. Each of Partner, on behalf of itself and its Affiliates (other than Excluded Partner Affiliates), and Calliditas, hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) It is duly organized and validly existing under the laws of the jurisdiction of its incorporation or formation, as applicable.

(b) It has the requisite corporate power and authority to conduct its business as presently being conducted and as proposed to be conducted by it.

(c) All corporate actions on its part, necessary for (i) the authorization, execution, delivery and performance by it of this Agreement, and (ii) the consummation of the transactions contemplated hereby, have been duly taken and it has the requisite corporate power and authority to enter into this Agreement and to perform its obligations contemplated hereunder.

(d) This Agreement constitutes a valid and binding obligation, enforceable against it in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable remedy of specific performance or injunctive relief is subject to the discretion of the court or other tribunal before which any proceeding may be brought).

(e) The execution, delivery and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and will not: (i) violate any provision of any Applicable Laws or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (ii) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound, or (iii) violate or conflict with any of the provisions of such Party's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents).

(f) Apart from expiration or termination of any applicable waiting periods (including any extensions thereof) required by any Applicable Laws or governmental entity for antitrust purposes in the Territory, there are no filings, consents, approvals, authorizations or other orders of, or notice to, any Governmental Authority or other Third Parties that are necessary to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement.

(g) To such Party's knowledge, neither it nor its officers, employees, agents, consultants or any other person used by such Party in the performance of the respective activities under this Agreement is: (i) debarred or disqualified under the FD&C Act; (ii) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; or (iii) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action.

10.2 Additional Representations and Warranties of Calliditas. Calliditas hereby further represents and warrants to Partner, as of the Effective Date, that except as set forth on **Schedule 5**:

(a) Calliditas is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement.

(b) **Schedule 3** contains a true, complete and accurate list of all Patents Controlled by Calliditas that (i) [***]; and (ii) [***].

(c) To Calliditas' knowledge (without having made any specific enquiry) and except as specifically disclosed by Calliditas in writing, there are no Patents, Know-How or other intellectual property rights of Calliditas, its Affiliates or Third Parties Covering (with respect to Patents) or otherwise claiming or protecting (with respect to Know-How or other intellectual property rights) the composition of matter, method of use, dosing, Manufacturing or formulation of the Product that [***].

(d) the Licensed Patents set forth on **Schedule 3** are in full force and effect and have been maintained to date.

(e) Calliditas has sufficient legal or beneficial title and ownership of, or sufficient rights under, the Licensed Intellectual Property to grant the licenses and other rights granted under such Licensed Intellectual Property to Partner pursuant to this Agreement, and, prior to the Effective Date, Calliditas has not granted any assignment options, pre-emptive or other rights to any Third Party that, if exercised by such Third Party, would conflict with the rights granted to Partner under this Agreement and neither Calliditas nor its Affiliates have abandoned the Licensed Patents or otherwise allowed them to lapse.

(f) None of the Licensed Intellectual Property is Controlled by Calliditas pursuant to an in-license agreement.

(g) To Calliditas' knowledge, the development, conception and reduction to practice of any and all Licensed Intellectual Property have not misappropriated trade secrets, Patents, Know-How or other intellectual property rights or property of any Third Party.

(h) Calliditas is fully able to comply with its obligations concerning Data Protection as set forth in Article 8.7.

(i) All post-approval commitments to the Regulatory Authorities related to the Conditional Regulatory Approval are set out in full in **Schedule 6**.

(j) The Clinical Trials relating to the Product conducted or sponsored by or on behalf of Calliditas or its Affiliates have not violated the Applicable Laws and, to the extent applicable, the Good Clinical Practice (GCP) determined by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in such a way that this would materially impact the grant of Conditional Regulatory Approval of the Product, or subsequent Unconditional Regulatory Approval of the Product. No Clinical Trial has been terminated or suspended prior to its natural completion, and in case of any study which is ongoing as at the Effective Date, there are to the best of the Calliditas' knowledge, no circumstances which are likely to result in such early termination or suspension.

(k) The pharmaceutical dossiers of the Product have not violated generally accepted pharmaceutical principles or the current state of science and technology in such a way that this would materially impact the grant of the Conditional Regulatory Approval of the Product, or subsequent Unconditional Regulatory Approval of the Product.

(l) Partner will have direct access to original data, the processes applied in the Clinical Trial and the "Essential Documents" as defined in ICH E6 (R2) provided that no access will be given to descriptions of the process used for coating of beads used in the Product nor other information related to the specifics of the manufacturing of the Product, and provided that the data arising from the Ongoing Clinical Trial will be made available only after the publication of the top line results of the Ongoing Clinical Trial.

(m) There is no (i) pending, or, to the knowledge of Calliditas, threatened, claim, interference, opposition, demand, suit, proceeding, arbitration or investigation by a Governmental Authority of a civil, criminal or regulatory nature against Calliditas, or (ii) judgment or settlement against or owed by Calliditas, in each case of the immediately foregoing (i) and (ii), in connection with the Licensed Intellectual Property, including any Third Party challenging the ownership, validity or scope of any Licensed Intellectual Property.

(n) To the knowledge of Calliditas (without having made any specific enquiry), the Commercialization of the Product in the Partner Territory will not infringe any existing issued Patent of any Third Party. Calliditas has not received any written notification from a Third Party that Commercialization of the Product infringes or misappropriates the Patents, Know-How or other intellectual property rights owned or otherwise controlled by such Third Party in the Partner Territory; there are no pending litigation, claims, judgments or settlements against Calliditas in respect of the Partner Territory or amounts due with respect any such claims and, to Calliditas' knowledge, no Third Party has any basis for any such claim.

(o) Calliditas has no actual knowledge that any Third Party is infringing or misappropriating the Licensed Intellectual Property in the Partner Territory and there are no pending litigation, claims, judgments or settlements against any Third Party or amounts due with respect any such claims.

(p) All information, documentation and other materials made available by Calliditas during the period of diligence prior to the Effective Date were provided in good faith, and are, to the best of Calliditas' knowledge, accurate and complete in all material respects, and accurately reflect in all material respects the documentation and materials prepared and used by Calliditas in its business activities in the ordinary course.

10.3 Additional Representations and Warranties of Partner. Partner, on behalf of itself and its Affiliates (other than Excluded Partner Affiliates) hereby further represents and warrants to Calliditas, as of the Effective Date:

(a) there are no pending, or to the knowledge of Partner, threatened, claims or disputes by any Person against it that would materially impair (i) Partner's ability to perform its obligations under this Agreement or (ii) Calliditas right to exploit the licenses and other rights granted by Partner to Calliditas under this Agreement; and

(b) Partner is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement.

10.4 Sanctions. Each Party herewith covenants that it shall and shall ensure that Persons associated with it or other Persons who are enjoying rights or performing services or providing Products in connection with this Agreement or the Supply Agreement shall:

(a) comply with all Applicable Laws, statutes and regulations in accordance with or in relation to this Agreement, including but not limited to any sanctions control regulations, including but not limited those of the United States of America, the European Union, Germany and the United Kingdom;

(b) guarantee that neither it nor its Affiliates or shareholder(s) or managers is a sanctioned person as defined under the applicable sanctions control regulations mentioned under (a) above;

(c) not do, or omit to do, any act that will cause or lead the other Party to be in breach of any of the sanctions control regulations mentioned under (a) above; and

(d) promptly report to the other Party if it becomes aware that either it or any of its Affiliates, managers or shareholder(s) or other Persons who are enjoying rights or performing services or providing Products in connection with this Agreement or the Supply Agreement are or may be in breach of the sanctions control regulations as mentioned under (a) above or become a listed/sanctioned person or organization on any sanctions list maintained by the United Nations, the European Union or the United States.

10.5 Prohibited Conduct. Each Party covenants to the other that such Party and its Affiliates and its and their employees and contractors will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly through Third Parties, to any Government Official for the purpose of: (a) improperly influencing any act or decision of the Person or Government Official; (b) inducing the Person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (c) securing any improper advantage; or (d) inducing the Person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist any Party in obtaining or retaining business. For the purpose of this Article 10.5 "**Government Official**" means: (x) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, or agency, of any Governmental Authority; (y) any candidate for political office, any political party or any official of a political party; or (z) any Person acting in an official capacity on behalf of any of the foregoing.

10.6 Ongoing Covenant of Calliditas. During the Term, Calliditas shall not enter into any agreement with a Third Party that conflicts with the rights and licenses granted by Calliditas to Partner under this Agreement.

10.7 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 10, EACH PARTY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE RESEARCH, DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

ARTICLE 11

INDEMNIFICATION AND LIMITATION OF LIABILITY

11.1 Indemnification by Partner. Subject to Article 11.3, Partner shall indemnify, defend and hold Calliditas, its Affiliates, and their respective directors, officers and employees (collectively, the "**Calliditas Indemnitees**") harmless from and against any and all costs, fees, expenses, losses, liabilities, and damages, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**") suffered or incurred by any Calliditas Indemnitee as a result of any claim, demand, action or other proceeding ("**Claims**") brought by a Third Party against a Calliditas Indemnitee, in each case to the extent to the extent such Claim and Losses arise out of: [***].

11.2 Indemnification by Calliditas. Subject to Article 11.3, Calliditas shall indemnify, defend and hold Partner, its Affiliates, and their respective directors, officers and employees (collectively, the "**Partner Indemnitees**") harmless from and against any and all Losses suffered or incurred by any Partner Indemnitee as a result of any Claim brought by a Third Party against a Partner Indemnitee, in each case to the extent to the extent such Claim and Losses arise out of: [***].

11.3 Indemnification Procedures. A Party seeking indemnification under Article 11.1 or 11.2 hereof for its applicable Calliditas Indemnitees or Partner Indemnitees (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of the Claim. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit, the Indemnitor to have complete control of the defense or settlement of such Claim (except as set forth below) so long as it promptly assumes the defense and prosecutes the defense or settlement with appropriate diligence and care. The Indemnitor shall have the authority, at its discretion, to settle any such Claim only with the prior written consent of the Indemnitee; provided, however, that such consent shall not be unreasonably withheld or delayed so long as such settlement does not adversely affect the Indemnitee's rights hereunder (including, as concerns Calliditas, its activities in the Calliditas Territory), or impose any obligations (whether as payment or otherwise) on the Indemnitee in addition to those set forth herein. At the cost of the Indemnitor, the Indemnitee and its directors, officers, employees and agents shall cooperate fully with the Indemnitor and its respective legal representatives in the investigation and defense of any Claim covered by this indemnification. The Indemnitor shall keep the Indemnitee reasonably informed of the progress of the action and shall consider the comments and observations of the Indemnitee timely given in the course of the proceedings. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its expense. Notwithstanding the foregoing, the Indemnitee may be represented by separate counsel at the expense of the Indemnitor if a conflict of interest exists between the interests of the Indemnitor and Indemnitee so that a single counsel representing Indemnitor cannot adequately defend the rights of the Indemnitee.

11.4 **Insurance**. Each Party shall maintain insurance with a creditworthy insurance company against [***].

11.5 **Limitation of Liability**. EXCEPT IN THE CASE OF (A) A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR (B) DEATH OR PERSONAL INJURY CAUSED BY A PARTY`S NEGLIGENCE, OR (C) A BREACH OF THE OBLIGATIONS OF A PARTY UNDER ARTICLE 8, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT. THE FOREGOING LIMITATION WILL NOT LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS TO THE OTHER PARTY UNDER ARTICLE 11 IN RESPECT OF ANY THIRD-PARTY CLAIM.

11.6 **Duty to Mitigate**. Each Party shall take, in relation to any fact, matter, event or circumstance which might give rise to a claim against the other Party all such reasonable steps and action as are necessary to avoid or mitigate the liability (or potential losses or damages) of such other Party in relation to such claim.

ARTICLE 12

TERM AND TERMINATION

12.1 **Term**. This Agreement shall be effective as of the Effective Date and, unless terminated earlier, this Agreement shall continue on a country-by-country basis until the date on which the Royalty Term has expired in such country and shall finally expire upon the expiration of the last-to-expire Royalty Term (the "**Term**").

12.2 **Termination**.

(a) **Mutual Agreement**. This Agreement may be terminated in its entirety at any time upon mutual written agreement between the Parties.

(b) **Termination by Partner for Convenience or by Calliditas for Cessation of Activities**.

(i) This Agreement may be terminated at any time by Partner upon eighteen (18) months' prior written notice to Calliditas.

(ii) This Agreement may be terminated by Calliditas upon written notice to Partner in the event that, [***].

(c) **Termination by Partner or Renegotiation for Material Event**. This Agreement may be terminated by Partner upon written notice to Calliditas with immediate effect (subject to Article 12.2(g)), if:

(i) [***]; or

(ii) [***]; or

(iii) [***], or

(iv) [***].

In the event that the Orphan Designation is revoked or otherwise terminates prematurely, the Parties will renegotiate in good faith and in reasonable time before the actual expiry of the Orphan Designation whether and how this Agreement shall continue, in particular with regard to the territorial exclusivity (Article 5.7) of this Agreement.

(d) **Challenge**. Calliditas may terminate this Agreement at any time upon written notice to Partner in the event that Partner or any of its Affiliates directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any patent or patent application within any of the Licensed Patents (a "**Patent Challenge**").

(e) **Material Breach**. Subject to Article 12.2(f), either Party may terminate this Agreement at any time upon written notice to the other Party if the other Party is in material breach of this Agreement and such material breach, if curable, is not cured within [***], so long as the breaching party is making a good faith effort to cure such breach. Termination shall not be the sole remedy for material breach of this Agreement, and a Party may choose to continue to perform hereunder and in response to any material breach may bring a claim for damages and other available remedies, and bringing such a claim shall not constitute a breach of this Agreement.

(f) **Failure to Use Commercially Reasonable Efforts**. [***].

(g) **Dispute.** Within [***] Business Days after receipt of:

(i) a notice of termination issued pursuant to Article 12.2(b)(ii), 12.2(c) or 12.2(e), but excluding in connection with alleged breach by Partner of its diligence obligation to use Commercially Reasonable Efforts to Commercialize the Product (which is the subject of Article 12.2(f)); or

(ii) a notice of continuation issued pursuant to Article 12.4;

if the recipient of such notice disputes in good faith the validity of such notice [***].

(h) **Insolvency**. Either Party may terminate this Agreement upon written notice to the other Party, if the other Party suffers an Insolvency Event.

(i) **No Rescission Rights**. Except as otherwise expressly provided for in this Agreement, the right of the Parties to terminate this Agreement or any right or remedy which would have a similar effect in connection with any breach of this Agreement (such as a claim for rescission of this Agreement) shall be excluded, and each Party waives any such right.

12.3 Consequences of Termination in Selected Termination Scenarios. Upon termination of this Agreement pursuant to Article 12.2 the following shall apply:

(a) **Termination of Licenses**. All licenses granted by Calliditas under this Agreement shall terminate.

(b) **New Partner IP License**. [***].

(c) **Sell Off of Product**. Partner shall have the right to sell off, for a period of up to [***] after the effective date of termination, all Product then in Partner's or its Affiliates' inventory, or on order from Calliditas (subject to the Supply Agreement), on the date on which the applicable notice of termination is provided; provided that Partner pays to Calliditas any payments due in accordance with this Agreement in connection with such sales.

(d) **Transfer of Clinical Trials**. [***].

(e) **Regulatory Submissions**. [***].

[***].

(f) **Copies of Data**. To the extent not already provided to Calliditas, Partner as promptly as reasonably practicable shall provide Calliditas with copies of all New Partner IP regarding the Product and the Partner Territory, and data collected or generated with respect to the Product in Partner's possession or Control.

(g) **Return of Confidential Information**. Each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to the other Party in writing as to such destruction) all of such other Party's Confidential Information that is in the possession or control of such Party (or any of its Affiliates, licensees or contractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party for legal purposes and will not be required to return or destroy back-up copies of electronic files provided that they are not accessed.

(h) **Trademarks**. [***].

(i) **Compensation Payments**. [***].

12.4 Partner Option to Continue Agreement. [***].

[***].

12.5 Further Effects of Expiration or Termination; Survival.

(a) **Termination of Rights and Obligations**. Except as set forth in this Article 12.5, all rights and obligations of the Parties under this Agreement will terminate as of the effective date of such termination.

(b) **Expiry**.

(i) Upon expiry of this Agreement pursuant to Article 12.1 (not early termination) for the Product in a particular country of the Partner Territory all licenses granted by Calliditas to Partner under this Agreement shall convert into irrevocable, perpetual, royalty free and fully paid-up licenses with respect to such Product in such country. Nothing in this Article 12.5(b) shall limit the consequences of early termination of this Agreement as set forth in Article 12.3.

(ii) Upon expiry of this Agreement pursuant to Article 12.1 (not early termination) in respect of all countries of the Partner Territory, subject to only the surviving terms and conditions of this Agreement, Calliditas, on behalf of itself and its Affiliates, hereby grants to Partner and its Affiliates (only for as long as they remain Affiliates of Partner and excluding Excluded Partner Affiliates) the rights in respect of Manufacture set out in Article 3.1(d), which rights shall be irrevocable, perpetual, royalty free and fully paid-up.

(c) **Accrued Obligations; Remedies**. Expiration or termination of this Agreement for any reason shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein. Except as otherwise expressly set forth herein, termination of this Agreement in accordance with and fulfillment of all obligations set forth in this Article 12 shall not affect any other rights or remedies that may be available to a Party in law or equity, all remedies being cumulative and not exclusive. For the avoidance of doubt, termination of this Agreement will not affect any Pharmacovigilance Agreement, which will continue to survive so long as any Products thereunder are being Commercialized.

(d) **Survival**. In addition to the termination consequences set forth in Article 12.3 (and any Articles referenced therein), the following provisions will survive expiration or termination of this Agreement for any reason: Article 1 (Definitions), Article 2.11(a), Articles 6.6 to 6.11, Article 8 (Confidentiality and Data Protection), Article 9 (Public Announcements and Use of Names), Article 11 (Indemnification and Limitation of Liability), Article 13 (Miscellaneous), Articles 7.1 to 7.3, Articles 12.3 and 12.5 and any other obligations and rights which are intended to survive this Agreement (whether expressly or due to their context and content).

ARTICLE 13

MISCELLANEOUS

13.1 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, in English, and shall be deemed given only when delivered to the Party either (i) personally or (ii) by courier, in each case to the address set out below or at such other address as such Party may from time to time specify by notice given in the manner provided herein to the Party entitled to receive notice hereunder. If transmitted via electronic mail, a hard copy shall be delivered personally or by registered mail in accordance with this clause.

For Calliditas:

Calliditas Therapeutics AB, at the addresses first noted above, and with a copy to [***].

For Partner:

STADA Arzneimittel AG, at the addresses first noted above, and with a copy to

Executive Vice President Europe (Steffen Wagner), [***], and

Executive Vice President Legal (Dr. Christoph Dengler),

[***].

13.2 Entire Agreement. This Agreement, the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement (including any Schedules or other attachments hereto or thereto and the agreements entered into hereunder and thereunder, as applicable) constitutes the entire agreement between the Parties with respect to the subject matter 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. All information disclosed by a Party during diligence regarding negotiation of this Agreement and the transactions related to this Agreement shall be deemed such Party's Confidential Information for the purposes of this Agreement. In case of conflicting provisions, the Quality Agreement shall prevail with respect to all matters relating to the quality assurance of the Products, the Supply Agreement (including the Product Schedule (as such term is defined under the Supply Agreement)) shall prevail with respect to all matters concerning the order, purchase, Manufacture and supply, storage, and shipping of Products by Calliditas to Partner, the Pharmacovigilance Agreement shall prevail with respect to all matters concerning the receipt, investigation, and reporting of complaints, adverse events, recalls, and any other information related to the safety of a Product and this Agreement shall prevail with respect to all other matters.

13.3 Assignment. Neither Party may assign or otherwise transfer its rights or obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, except that:

(a) Partner hereby gives consent to Calliditas' entitlement to assign, without Partner's further prior written consent, this Agreement and its rights and obligations hereunder in whole or in part to (i) an Affiliate, or (ii) a Third Party that acquires, by or otherwise in connection with, a merger, sale of assets or stock, reorganization, consolidation or otherwise, all or substantially all of the Licensed Intellectual Property.

(b) Calliditas hereby gives consent to Partner's entitlement to assign, without Calliditas' further prior written consent, this Agreement and its rights and obligations hereunder as a whole (but not in part) to (i) an Affiliate (only for so long as such entity remains an Affiliate of Partner and excluding Excluded Partner Affiliates); or (ii) a Third Party that acquires, by or otherwise in connection with, a merger, sale of assets or stock, reorganization, consolidation or otherwise, all or substantially all of the business, assets, personnel, contracts and resources of the business unit primarily involved in implementation of Partner's performance obligations under this Agreement (provided that such business unit is also the business unit primarily involved in the commercialization of other products, and all rights and obligations with respect to such other products are also being acquired by such Third Party).

Any assignment of the rights or obligations under this Agreement in violation of this Article 13.2 shall be null and void. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

13.4 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented or delayed by Force Majeure and the nonperforming Party promptly provides notice of the prevention or delay to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to minimize the effect of and overcome or remove the cause or condition causing such Force Majeure. For purposes of this Agreement, "Force Majeure" shall mean an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided, that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party.

13.5 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.

13.6 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.

13.7 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.

13.8 No Third-Party Beneficiaries. Except as provided in Article 11 in respect to Calliditas Indemnitees and Partner Indemnitees, nothing in this Agreement, either express or implied, is intended to or shall confer upon any Third Party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

13.9 Amendment. This Agreement may not be amended or modified except by an instrument in writing signed by authorized representatives of Partner and Calliditas.

13.10 Governing Law. This Agreement will be governed by and interpreted under the laws of England and Wales. Any dispute, controversy, claim or difference of any kind whatsoever arising out of or in connection with this Agreement will be resolved exclusively in accordance with Article 13.10 provided, however, that all questions concerning the construction or effect of Patents will be determined in accordance with the laws of the country or other jurisdiction in which the particular patent within such Patents has been filed or granted, as the case may be. Any communication or proceedings resulting from disputes under this Agreement will be in English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods (1980).

13.11 Dispute Resolution; Jurisdiction.

(a) **Disputes**. Except as otherwise expressly set forth in this Agreement, in the event of any dispute under, relating to or in connection with this Agreement or its existence, construction, negotiation, performance, termination or validity, (a "**Dispute**"), the Parties shall refer such Dispute to the Applicable Senior Officers for attempted resolution by good faith negotiations within [***] after such referral is made. If the Applicable Senior Officers are unable to resolve the Dispute within the time allotted, either Party may proceed as set forth below in Article 13.11(b).

(b) **Jurisdiction**. Subject to Article 13.11(a), any Dispute shall be referred to and finally resolved by arbitration under the Rules of Arbitration of the International Chamber of Commerce by one (1) or more arbitrators appointed in accordance with the said Rules. The seat, or legal place, of arbitration shall be London, United Kingdom. The language to be used in the arbitral proceedings shall be English.

(c) **Conservatory, Emergency, or Interim Relief**. Nothing in this Article 13.11 shall prevent a Party from seeking conservatory, emergency, or interim relief not available from such arbitrators in any court of competent jurisdiction.

13.12 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.

13.13 Interpretation. Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" (or "includes without limitation"). The word "or" is used in the inclusive sense (and/or). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Articles and Exhibits in this Agreement are to Articles and Exhibits of this Agreement. References to any Articles include Articles and subsections that are part of the related Article (e.g., an Article numbered "Article 2.1" would be part of "Article 2", and references to "Article 2" would also refer to material contained in the subsection described as "Article 2.1").

13.14 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.

[SIGNATURES FOLLOW ON NEXT PAGE]

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.

Calliditas Therapeutics AB

By: _____
Name: Renee Aguiar-Lucander
Title: CEO

STADA Arzneimittel AG

By: _____
Name: [***]
Title: CEO

By: _____
Name: [***]
Title: EVP Global Legal / General Counsel

Schedule 1

Calliditas Trademarks

[***]

Schedule 2

Formula for Calculation of Net Sales in Case of Combination or Combined Dosage Therapy Products

[***]

Schedule 3

Licensed Patents

[***]

Schedule 4

Press Releases

Stockholm, Sweden **July 21, 2021**

Calliditas Therapeutics and STADA partner to register and commercialize specialty therapy for IgA Nephropathy in Europe

- **Calliditas and STADA partner to bring a specialty therapy focused on downregulating IgA1 to European patients. If approved, it would be the first-ever approved treatment in the EU for chronic autoimmune kidney disease IgA Nephropathy (IgAN)**
- **Partnership for this oral orphan-drug candidate combines Calliditas' drug-delivery expertise with STADA's pan-European marketing and sales expertise, including for specialty and nephrology medicines**
- **Deal covering European Economic Area (EEA) member states, Switzerland and the UK is valued at a total of 97.5 million EUR ($115m), plus royalties**

Stockholm, Sweden; Bad Vilbel, Germany. 21 July 2021 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") and STADA Arzneimittel AG ("STADA") announced today that they have entered into a license agreement to register and commercialize a novel specialty drug candidate for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in the European Economic Area (EEA) member states, Switzerland and the UK.

Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of 20M EUR ($24m) upon signing and up to an additional 77.5M EUR ($91m) in future payments linked to pre-defined regulatory and commercialization milestones. STADA is also obligated pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

The partnership relates to a novel oral formulation, developed under the project name 'Nefecon', of a potent and well-known active substance – budesonide – designed to target down regulation of IgA1 with a view to be disease modifying. If approved, this value-added specialty medicine, which received an EU orphan-drug designation in 2016, would be the first treatment authorized in the European Union for IgAN, a rare autoimmune disease. IgAN, also known as Berger´s disease, is a serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end stage renal disease and thus requiring dialysis or a kidney transplant. Prevalence in Europe is estimated at 4 in 10,000, translating into approximately 200,000 patients.

"We are excited to be entering into this partnership with STADA to bring this IgAN therapy to market in Europe, where there is a significant unmet medical need for this patient population. We look forward to working in close collaboration with STADA to pursue marketing authorization with the goal of bringing the first ever EU-approved medication in IgAN to patients as soon as possible, utilizing STADA's extensive marketing and sales platform throughout Europe," said Renée Aguiar-Lucander, CEO of Calliditas.

"This partnership, which leverages Calliditas' drug-delivery expertise and clinical data in this under-served patient population, further validates STADA's position as a go-to-partner for specialty pharmaceuticals, as well as for generics and consumer health products," commented STADA CEO Peter Goldschmidt. "This value-added novel formulation for a large orphan indication will complement STADA's offerings in nephrology, where we have built strong expertise over more than a decade through our epoetin zeta biosimilar and where we continue to place a clear strategic focus on seeking further opportunities to bring new options to patients."

The novel formulation is designed to deliver the drug to the Peyer's patch region of the lower small intestine, where the disease originates as per the predominant pathogenesis models. The formulation uses a unique two-step technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse like fashion only when it reaches the ileum in the lower small intestine. In addition to its potent local effect, another advantage of using this active substance is that it has very low bioavailability, with around 90% being inactivated in the liver before it reaches the systemic circulation. This means that a high concentration can be applied locally where needed, whilst limiting systemic exposure.

On May 28, 2021, Calliditas announced that the company had, under the drug-development candidate name Nefecon, submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for a novel oral formulation of budesonide targeting down regulation of IgA1 for the treatment of primary IgAN. The company also filed an application for accelerated approval in the US on March 15, 2021 and was granted priority review in April 2021. The commercial brand name for this therapy in Europe will be determined and disclosed at a later date.

Calliditas´ oral formulation has been granted Accelerated Assessment procedure by the Committee for Human Medicinal Products (CHMP) within the European Medicines Agency, which is intended to expedite access to drugs that the CHMP considers to be of major therapeutic interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Accelerated assessment reduces the maximum timeframe for review of the MAA to 150 days (excluding clock-stops).

IgAN is designated as an orphan disease in both the US and Europe. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment. Orphan incentives consist of ten years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.

If approved, the product could be available to patients in Europe in the first half of 2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease modifying.

Torreya acted as exclusive financial advisor to Calliditas on the transaction.

For further information, please contact:

Marie Galay, IR Manager, Calliditas
Tel.: +44 79 55 12 98 45, email: marie.galay@calliditas.com

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For Investor & Creditor Relations, email: ir@stada.de
Or visit us on the Internet at www.stada.com/investor-relations

The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the Calliditas contact person set out above, on July 21, 2021 at 8:30 a.m. CET.

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2020, STADA achieved group sales of EUR 3,010.3 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 713.3 million. As of December 31, 2020, STADA employed 12,301 people worldwide.

About Calliditas

Calliditas Therapeutics is a biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans, regulatory submissions and focus, as well as Calliditas's partnership with STADA, the parties' plans with respect to registration and commercialization of the specialty therapy, the terms of the collaboration and the intended benefits therefrom, the regulatory pathway and interactions for Nefecon, including timing of review and assessment of the candidate, and the intended benefits of regulatory designations such as Accelerated Assessment and orphan disease. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, the conduct of Calliditas's partnership with STADA, the potential for regulatory acceptance for and the success and timeline of its regulatory marketing application for Nefecon, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Calliditas Therapeutics and STADA partner to register and commercialize specialty therapy for IgA Nephropathy in Europe

- Calliditas and STADA partner to bring a specialty therapy focused on downregulating IgA1 to European patients. If approved, it would be the first-ever approved treatment in the EU for chronic autoimmune kidney disease IgA Nephropathy (IgAN)

- Partnership for this oral orphan-drug candidate combines Calliditas' drug-delivery expertise with STADA's go-to-partner strategy and pan-European marketing and sales expertise, including for specialty and nephrology medicines

- Deal covering European Economic Area (EEA) member states, Switzerland and the UK is valued at a total of EUR 97.5 million ($115m), plus royalties

Stockholm, Sweden; Bad Vilbel, Germany, 21 July 2021 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") and STADA Arzneimittel AG ("STADA") announced today that they have entered into a license agreement to register and commercialize a novel specialty drug candidate for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in the European Economic Area (EEA) member states, Switzerland and the UK.

The partnership relates to a novel oral formulation, developed under the projectname Nefecon, of a potent and well-known active substance – budesonide – designed to target down regulation of IgA1 with a view to be disease-modifying. If approved, this value-added specialty medicine, which received an EU orphan-drug designation in 2016, would be the first treatment authorised in the European Union for IgAN, a rare autoimmune disease. IgAN, also known as Berger's disease, is a serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end-stage renal disease and thus requiring dialysis or a kidney transplant.[1] Prevalence in Europe is estimated at 4 in 10,000, translating into approximately 200,000 patients.

"This partnership, which leverages Calliditas' drug-delivery expertise and clinical data in this under-served patient population, further validates STADA's position as a go-to-partner for specialty pharmaceuticals, as well as for generics and consumer health products," commented STADA CEO Peter Goldschmidt. "This value-added novel formulation for a large orphan indication will complement STADA's offerings in nephrology, where we have built strong expertise over more than a decade through our epoetin zeta biosimilar and where we continue to place a clear strategic focus on seeking further opportunities to bring new options to patients."

[1] EU/3/16/1778 | European Medicines Agency (europa.eu)

“We are excited to be entering into this partnership with STADA to bring this IgAN therapy to market in Europe, where there is a significant unmet medical need for this patient population. We look forward to working in close collaboration with STADA to pursue marketing authorisation with the goal of bringing the first ever EU-approved medication in IgAN to patients as soon as possible, utilizing STADA’s extensive marketing and sales platform throughout Europe,” said Renée Aguiar-Lucander, CEO of Calliditas.

The novel formulation is designed to deliver the drug to the Peyer’s patch region of the lower small intestine, where the disease originates as per the predominant pathogenesis models. The formulation uses a unique two-step technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse-like fashion only when it reaches the ilium in the lower small intestine.

In addition to its potent local effect, another advantage of using this active substance is that it has very low bioavailability, with around 90% being inactivated in the liver before it reaches the systemic circulation. This means that a high concentration can be applied locally where needed, whilst limiting systemic exposure.

On 28 May 2021, Calliditas announced that the company had, under the drug-development candidate name Nefecon, submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for a novel oral formulation of budesonide targeting down regulation of IgA1 for the treatment of primary IgAN. The company also filed an application for accelerated approval in the US on March 15, 2021 and was granted priority review in April 2021. The commercial brand name for this therapy in Europe will be determined and disclosed at a later date.

Calliditas’ oral formulation has been granted Accelerated Assessment procedure by the Committee for Human Medicinal Products (CHMP) within the European Medicines Agency, which is intended to expedite access to drugs that the CHMP considers to be of major therapeutic interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Accelerated assessment reduces the maximum timeframe for review of the MAA to 150 days (excluding clock-stops)[2].

IgAN is designated as an orphan disease in both the US and Europe. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment[3]. Orphan incentives consist of 10 years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.

If approved, the product could be available to patients in Europe in the first half of 2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease-modifying.

Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of EUR 20m ($24m) upon signing and up to an additional EUR 77.5m ($91m) in future payments linked to pre-defined regulatory and commercialization milestones.

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2020, STADA achieved group sales of EUR 3,010.3 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 713.3 million. As of 31 December 2020, STADA employed 12,301 people worldwide.

About Calliditas Therapeutics
Calliditas Therapeutics is a biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

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[2] Accelerated assessment | European Medicines Agency (europa.eu)

[3] Orphan designation: Overview | European Medicines Agency (europa.eu)

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Schedule 5

Exceptions to Representation and Warranties of Calliditas

[***]

Schedule 6

Commitments to the Regulatory Authorities

[***]

Schedule 7

Expert Determination Procedure

[***]

Exhibit 99.1

Stockholm, Sweden **July 21, 2021**

Calliditas Therapeutics and STADA partner to register and commercialize specialty therapy for IgA Nephropathy in Europe

- **Calliditas and STADA partner to bring a specialty therapy focused on downregulating IgA1 to European patients. If approved, it would be the first-ever approved treatment in the EU for chronic autoimmune kidney disease IgA Nephropathy (IgAN)**
- **Partnership for this oral orphan-drug candidate combines Calliditas' drug-delivery expertise with STADA's pan-European marketing and sales expertise, including for specialty and nephrology medicines**
- **Deal covering European Economic Area (EEA) member states, Switzerland and the UK is valued at a total of 97.5 million EUR ($115m), plus royalties**

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The partnership relates to a novel oral formulation, developed under the project name 'Nefecon', of a potent and well-known active substance – budesonide – designed to target down regulation of IgA1 with a view to be disease modifying. If approved, this value-added specialty medicine, which received an EU orphan-drug designation in 2016, would be the first treatment authorized in the European Union for IgAN, a rare autoimmune disease. IgAN, also known as Berger´s disease, is a serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end stage renal disease and thus requiring dialysis or a kidney transplant. Prevalence in Europe is estimated at 4 in 10,000, translating into approximately 200,000 patients.

"We are excited to be entering into this partnership with STADA to bring this IgAN therapy to market in Europe, where there is a significant unmet medical need for this patient population. We look forward to working in close collaboration with STADA to pursue marketing authorization with the goal of bringing the first ever EU-approved medication in IgAN to patients as soon as possible, utilizing STADA's extensive marketing and sales platform throughout Europe," said Renée Aguiar-Lucander, CEO of Calliditas.

"This partnership, which leverages Calliditas' drug-delivery expertise and clinical data in this under-served patient population, further validates STADA's position as a go-to-partner for specialty pharmaceuticals, as well as for generics and consumer health products," commented STADA CEO Peter Goldschmidt. "This value-added novel formulation for a large orphan indication will complement STADA's offerings in nephrology, where we have built strong expertise over more than a decade through our epoetin zeta biosimilar and where we continue to place a clear strategic focus on seeking further opportunities to bring new options to patients."

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If approved, the product could be available to patients in Europe in the first half of 2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease modifying.

Torreya acted as exclusive financial advisor to Calliditas on the transaction.

For further information, please contact:

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The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the Calliditas contact person set out above, on July 21, 2021 at 8:45 a.m. CET.

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