

# SECURITIES AND EXCHANGE COMMISSION

## FORM 6-K

Current report of foreign issuer pursuant to Rules 13a-16 and 15d-16 Amendments

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### FILER

#### **Aeterna Zentaris Inc.**

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SIC: **2834** Pharmaceutical preparations

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

**FORM 6-K**

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

For the month of December 2020

Commission File Number: **001-38064**

**Aeterna Zentaris Inc.**

(Translation of registrant's name into English)

**315 Sigma Drive, Summerville, South Carolina, USA 29486**

(Address of 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):

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Exhibit 99.1 included with this report on Form 6-K is hereby incorporated by reference into the Registrant's Registration Statements on Form F-3 (File No. 333-232935) and Forms S-8 (File Nos. 333-224737, 333-210561, 333-200834) and shall be deemed to be a part thereof from the date on which this report is furnished, to the extent not superseded by documents or reports subsequently filed or furnished.

**DOCUMENTS INDEX**

<b>Exhibit</b>	<b>Description</b>
99.1	<a href="#">License Agreement, effective December 7, 2020, by and between Aeterna Zentaris GmbH and Consilient Health Ltd.</a>

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**SIGNATURE**

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.

**AETERNA ZENTARIS INC.**

Date: December 7, 2020

By: */s/ Klaus Paulini*

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Klaus Paulini  
President and Chief Executive Officer

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## License Agreement

between

Aeterna Zentaris GmbH, a corporation incorporated under the laws of Germany, (“**AEZS**”), with its principal place of business at Weismüllerstrasse 50, 60314 Frankfurt am Main Germany;

and

Consilient Health Ltd, a corporation incorporated under the Laws of Ireland, (“**CH**”), with its registered office at 5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland,

each a “**Party**”, and together the “**Parties**”.

## Preamble

AEZS owns or controls proprietary rights with respect to the Licensed Product - an oral growth hormone secretagogue receptor agonist indicated for the diagnosis of growth hormone deficiency (GHD) in adults and approved by the European Commission. AEZS has also commenced a clinical programme to extend the indication to include Paediatric Use (as defined below) and intends to start and conduct the PCT (as defined below).

AEZS desires to license the rights to the Licensed Product (“**License**”) including Marketing Authorisations (as defined below) and is willing to retain supply chain management and responsibility for the finished goods and active pharmaceutical ingredients.

CH desires to commercialise the Licensed Product supplied by AEZS in the Field and in the Territory.

## 1 Definitions

1.1 “**Active Sales**” shall mean, in relation to a territory:

actively to approach individual customers inside that territory through direct mail (including the sending of unsolicited (i) emails) or visits and/or through advertisement in media or other promotions specifically targeted at customers in that territory;

online advertisements addressed to customers in that territory and other efforts to be found specifically by customers in (ii) that territory, including the use of territory-based banners on third party websites and paying a search engine or online advertisement provider to have advertisements or higher search rankings displayed specifically to users in that territory;

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advertising or promotion in any form, or translation of CH’s website into a language other than an official language of (iii) the Territory, that CH would not reasonably carry out but for the likelihood that it will reach customers in that territory; and/or

(iv) to effect sales through the creation of a warehouse or distribution centre or other operations in that territory,

but excludes Passive Sales.

1.2 “**Affiliate**” shall mean and include in relation to each Party, any person, firm, corporation or other entity: (i) if at least fifty percent (50 %) of the voting stock or other equity interest thereof is owned, directly or indirectly, by that Party; (ii) which owns, directly or indirectly, at least fifty percent (50 %) of the voting stock or other equity interest of that Party; or (iii) if at least fifty

percent (50 %) of the voting stock or other equity interest thereof is owned, directly or indirectly, by a person, firm, corporation or other entity that owns, directly or indirectly, at least fifty percent (50 %) of the voting stock or other equity interest of that Party.

1.3 “**Agreement**” shall mean this License Agreement and all Exhibits attached hereto, and the terms „herein”, „hereunder”, „hereto” and such similar expressions shall refer to this Agreement.

1.4 “**Applicable Law(s)**” shall mean the provisions of all statutes, laws, rules, regulations, administrative codes, permits and licenses applicable to this Agreement or the activities contemplated hereunder.

1.5 “**Business Plan**” means the annual commercialisation plan for the Licensed Products containing, inter alia, information relating to the pricing, reimbursement, marketing, promotion and selling of the Licensed Product including but not limited to (i) CH’s Commercialisation plans; (ii) information relating to any pharmacoeconomic studies CH intends to conduct to justify pricing; (iii) analysis of competitive products and environment, including details of any market research CH intends to conduct; (iv) intended product positioning strategies and promotional strategies; (v) approach to pricing approval; (vi) medical education strategies; and (viii) sales forecasts and any associated timelines, the initial version to be prepared and submitted by CH within three (3) months following the Effective Date, as updated from time to time in accordance with Section 6.

1.6 “**Breaching Party**” shall have the meaning ascribed to it in Section 17.2.

1.7 “[Redacted] Agreement” means the [Redacted].

1.8 “**Commercialise**” or “**Commercialisation**” means any and all activities directed to commercialization, including marketing, promoting, detailing, importing, distributing, warehousing, offering for sale, having sold and/or selling a pharmaceutical product, including market research, pre-launch marketing and educational activities, and sampling.

1.9 “**Commercially Reasonable Efforts**” shall mean efforts consistent with commercial and good business practice and comparable with efforts customarily used in the pharmaceutical industry by pharmaceutical companies for products at a similar stage of development and approval status and with equivalent economic value, and considering the relevant regulatory, legal, business, medical, scientific and commercial circumstances.

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1.10 “**Compound**” shall mean the active pharmaceutical ingredient macimorelin acetate.

1.11 “**Confidential Information**” shall mean and include all Licensed Know How and all other know how, data and information of the Disclosing Party, whether or not they are marked as confidential and whether they are communicated orally or in writing, which is not generally known in the public and which relates to the Licensed Product, the Improvements, the Field or the business, research and development activities and results, finances, contractual relationships and operations of the Disclosing Party.

1.12 “**Data Package**” shall mean the data for the Existing Regulatory Approvals as further described in Exhibit 1.12.

1.13 “**Development**” (and the corresponding verb “**to Develop**”) means all development and regulatory activities regarding the Licensed Product in the Territory, including preparing, submitting, reviewing or developing data or information necessary for the purpose of submission to a Regulatory Authority to obtain or maintain and/or expand Regulatory Approval of the Licensed Product or any Improvements in the Territory including data management, statistical designs and document preparation.

1.14 “**Disclosing Party**” shall have the meaning ascribed to it in Section 19.1.

1.15 “**Effective Date**” of this Agreement shall mean December 7, 2020.

1.16 “**EMA**” means the European Medicines Agency.

1.17 “**Evidence and Cure Periods**” shall have the meaning ascribed to it in Section 14.1.

1.18 “**Existing Regulatory Approvals**” shall have the meaning ascribed to it in Section 4.1 and further described in Exhibit 1.18.

- 1.19 “**FDA**” means the U.S. Food and Drug Administration.
- 1.20 “**Field**” shall mean the diagnosis of human growth hormone deficiency in adults, the Paediatric Use and any and all further diagnostic uses of the Licensed Product. Field shall not cover any therapeutic uses of the Licensed Product.
- 1.21 “**First Commercial Sale Date**” means the date of the first commercial sale in an arm’s length transaction to a Third Party of the Licensed Product in each country in the Territory by or on behalf of CH, an Affiliate, sub-licensee or licensee after obtaining Regulatory Approval and any Pricing Approvals for the Licensed Product necessary or desirable in such country.
- 1.22 “**Generic Competition**” shall mean on a country-by-country basis, with respect to the Licensed Product in a country of the Territory, if throughout a given calendar quarter one or more Generic Equivalents are commercially available in such country.
- 1.23 “**Generic Equivalent**” shall mean, with respect to the Licensed Product, any pharmaceutical product that (a) contains the same active pharmaceutical ingredient and; (b) is sold in any country of Territory by a Third Party that is not CH or sublicensee of CH, under a marketing authorisation granted by the Regulatory Authority to such Third Party, and without infringing any Licensed Patents or applicable regulatory exclusivity provisions.
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- 1.24 “**GHD Test**” shall mean a growth hormone deficiency test conducted using the Licensed Product.
- 1.25 “**Improvements**” to the Licensed Product shall mean and include any and all inventions, and any and all changes, modifications and amendments to the Licensed Rights which:
- (i) improve the performance or efficacy of the Licensed Product;
  - (ii) reduce any side effects or other adverse effects of the Licensed Product;
  - (iii) reduce the cost and/or increase the efficiency or productivity of the Manufacturing processes for the Licensed Product;
  - (iv) improve the shelf life of the Licensed Product;
  - (v) combine the Licensed Product with any other active ingredient for diagnostic purposes or any other diagnostic use; or
  - (vi) otherwise relate to the use of the Licensed Product within the Field,
- and all IPR relating to any such improvements.
- 1.26 “**IPR**” shall mean all registered or unregistered intellectual property rights (e.g. patents, trademarks, designs and utility rights, including the respective applications) and includes, by way of example, but without limitation, know-how, trade secrets, formulae, Manufacturing processes, tests results, designs, sketches, photographs, plans, drawings, specifications, samples, reports, studies, findings, inventions and ideas.
- 1.27 “**Joint Inventions**” shall have the meaning ascribed to it in Section 12.6.
- 1.28 “**Launch**” shall mean the first date as of which sales of the Licensed Product shall, in compliance with the Applicable Law, be carried out within the Territory.
- 1.29 “**License**” shall have the meaning ascribed to it in Section 2.1.
- 1.30 “**License Fee**” shall have the meaning ascribed to it in Section 10.4.
- 1.31 “**Licensed Know How**” shall mean all of the know how related to the Licensed Product to which AEZS has rights as at the Effective Date. Without limiting the generality of the definition set forth in this Section 1.31 , the Licensed Know How existing as of the Effective Date is described in more detail in Exhibit 1.31 hereto and shall include the Data Package.

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1.32 **“Licensed Patent Rights”** shall mean (i) all patents, patent applications, divisions, continuations, continuation-in-part applications, divisionals, extensions, substitutions, renewals, confirmations, supplementary protection certificates and reissues that are owned or licensed by AEZS on the Effective Date and are necessary or useful to Develop, Manufacture and/or Commercialise the Licensed Product; and (ii) all patents, patent applications, divisions, continuations, continuation-in-part applications, divisionals, extensions, substitutions, renewals, confirmations, supplementary protection certificates and reissues owned by or licensed to AEZS at any time during the Term and which are based on or derive priority from the patents, patent applications, divisions, continuations, continuation-in-part applications, divisionals, extensions, substitutions, renewals, confirmations, supplementary protection certificates and reissues referred to in (i). AEZS’s patent rights as at the Effective Date are listed in more detail in Exhibit 1.32 hereto.

1.33 **“Licensed Product”** shall mean Macimorelin acetate 60 mg granules for oral suspension in sachet, and any and all other forms of administration, pack sizes, and presentations of the Compound for use in the Field.

1.34 **“Licensed Rights”** shall mean the Licensed TMs (if any), the Licensed Know How, the Licensed Patent Rights and any Improvements.

1.35 **“Licensed TMs”** shall mean (if any) any and all trade marks, trade names, logos, and other symbols of designation (whether or not registered or registrable) that are owned or licensed by AEZS on the Effective Date and which relate to the Product. AEZS’s trade marks are listed in more detail in Exhibit 1.35.

1.36 **“Marketing Authorisation”** shall mean all such Regulatory Approvals granted by Regulatory Authorities that are necessary in order to promote, distribute and sell the Licensed Product in the Territory and shall also mean any and all future registrations, licenses, permits and approvals including all non-granted applications required for the marketing, sales and distribution of the Licensed Product in the Territory. Without limiting the generality of the definition set forth in this Section 1.36, the Marketing Authorisations existing as of the Effective Date are listed in Exhibit 1.36.

1.37 **“Manufacture”** or **“Manufacturing”** means to make, have made, produce, manufacture, process, fill, finish, package, label, perform quality control testing, perform quality assurance, release procedures, ship or store a compound or product or any component thereof. When used as a noun, **“Manufacture”** or **“Manufacturing”** means any and all activities involved in Manufacturing Licensed Product or any component thereof.

1.38 **“Net Sales”** shall mean the amount invoiced by CH, its Affiliates, its sublicensees or distributors on account of sales of the Licensed Product to Third Parties less the following deductions to the extent actually allowed or specifically allocated to the Licensed Product by the selling party using generally accepted accounting standards:

- (i) sales and excise taxes and duties paid or allowed by the selling party and any other governmental charges imposed upon the Manufacturing, importation, use or sale of such Licensed Product;
- (ii) customary trade, quantity and cash discounts allowed on Licensed Product;

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(iii) allowances or credits to customers on account of rejection or return of Licensed Product or on account of retroactive price reductions affecting the Licensed Product;

(iv) freight and insurance costs, if they are included in the selling price for the Licensed Product invoiced to Third Parties, provided always that such deduction shall not be greater than the balance between the selling price actually invoiced to the Third Party and the standard selling price which would have been charged to such Third Party for the Licensed Product exclusive of freight and insurance in the respective country; and

(v) an amount equal to bad debts properly deducted in accordance with generally accepted accounting practices, subject to a maximum deduction for bad debts of 5% in any calendar year.

For the avoidance of doubt, for the Licensed Product the Net Sales shall be calculated only once for the First Commercial Sale of the Licensed Product by either CH, its Affiliate, its sublicensee or its distributor, as the case may be, to a Third Party which is neither an Affiliate, sublicensee or distributor of CH.

In the event of combination products, i. e., the Licensed Product which contains other protected materials or other technologies for which CH requires a Third Party license, the Net Sales shall be reduced by multiplying the Net Sales by the fraction  $A/(A+B)$  where “A” is the Net Sales price of the Licensed Products hereunder when sold without combination in the relevant country (or if not sold in the relevant country without combination, when sold without combination in a comparable country) or where not sold without combination in the relevant country or any comparable country, a fair market price for the Licensed Product and “B” is the marketed list price of such other product in the combination when sold without combination in the relevant country (or if not sold in the relevant country without combination, when sold without combination in any comparable country) or where not sold without combination in the relevant country or any comparable country, a fair market price for such product.

- 1.39 “**Non-Breaching Party**” shall have the meaning ascribed to it in Section 17.2.
- 1.40 “**Paediatric Use**” shall mean the use of the Licensed Product to diagnose growth hormone deficiency in patients aged 2 to 18 years.
- 1.41 “**Passive Sales**” shall mean, in relation to a territory:
- (i) responding to unsolicited requests from individual customers;
  - (ii) sales received through the use of general advertisement or media; and/or
  - (iii) sales received through the general advertisement or promotion on the internet not targeted at that territory.
- 1.42 “**PCT**” shall mean the clinical trial with the reference AEZS-130-P02 to be conducted by AEZS as the sponsor for the Paediatric Use.
- 1.43 “**Pharmacovigilance Agreement**” shall have the meaning ascribed to it in Section 8.
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- 1.44 “**Pricing and Reimbursement Approval(s)**” shall mean an approval, agreement, determination or governmental decision establishing prices for the Licensed Product that can be charged and will be reimbursed by government authorities or otherwise in countries in the Territory where government authorities or government authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.
- 1.45 “**Product Specification**” shall mean the specification for the Licensed Product as detailed in Exhibit 1.45.
- 1.46 “**Product Trademarks**” shall mean the trademarks used by CH for the Licensed Product.
- 1.47 “**Promotional Material**” means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave-behind items, reprints, direct mail, and advertisements intended for use or used by or on behalf of CH or its Affiliates in connection with any promotion of the Licensed Product.
- 1.48 “**Quality Agreement**” shall have the meaning ascribed to it in Section 7.
- 1.49 “**Recall**” shall have the meaning ascribed to it in Section 9.
- 1.50 “**Receiving Party**” shall have the meaning ascribed to it in Section 19.1.
- 1.51 “**Regulatory Approvals**” shall mean any marketing authorisations, registrations, certifications, rights, licenses or other approvals granted by any Regulatory Authority and necessary for the Manufacturing, testing, marketing and sale of pharmaceutical products in any country, including positive assessments or statements by any ethics committee or any equivalent review board.



- 1.52 “**Regulatory Authority**” shall mean any supranational, national or local parliament, regional, state, county, city, town, village, municipal, district, commission, department or agency including FDA, EMA, or any competent authority in the EU, Europe or the United Kingdom or other country in which the Licensed Product holds Marketing Authorisation, authority (including a listing authority in relation to a stock exchange), inspectorate, minister, ministry official, or other public or statutory Person (whether autonomous or not), multinational organisation or any other body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power of any nature over the Parties.
- 1.53 “**Steering Committee**” shall mean the committee described in Section 5.1, which is composed of representatives from both Parties.
- 1.54 “**Sublicense Income**” shall mean consideration in any form other than running royalties on Net Sales that CH or an Affiliate receives from a sublicensee of the Licensed Rights or its Affiliates. Sublicense Income shall include any upfront payments, license or option fees, lump sum payment, equity securities, milestone payments and other payments. In the event CH or any of its Affiliates receives monetizable, non-cash consideration in connection with a sublicense, Sublicense Income shall be calculated based on the fair market value of such consideration at the time of the transaction, assuming an arm’s length transaction made in the ordinary course of business.
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- 1.55 “**Supply Agreement**” shall have the meaning ascribed to it in Section 7.
- 1.56 “**Term**” shall have the meaning ascribed to it in Section 17.1.
- 1.57 “**Territory**” shall mean and include the European Economic Area and the United Kingdom in which CH is allowed to use the Licensed Rights. The current list of countries is specified in Exhibit 1.57.
- 1.58 “**Third Party**” shall mean any party that is independent from CH and its Affiliates and AEZS and its Affiliates.
- 1.59 “**Valid Claim**” shall mean:
- (i) any claim of an issued and unexpired Licensed Patent Right, which has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction in a decision that is not appealed or cannot be appealed, and which has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise, or
  - (ii) a pending claim in a pending patent application within the Licensed Patent Rights.
- 1.60 Unless the context otherwise requires, any reference in this Agreement to:
- (i) a “**Section**” is to the relevant section of this Agreement;
  - (ii) a “**paragraph**” is to the relevant paragraph of the specified Exhibit to this Agreement;
  - (iii) this Agreement shall include the Exhibits hereto;
  - (iv) the singular shall be deemed to include the plural and vice versa;
  - (v) words denoting any gender shall include all genders and words denoting persons shall include bodies corporate and vice versa;
  - (vi) any provision of a statute shall be construed as a reference to that provision as amended, modified, re-enacted or extended from time to time;
  - (vii) except as expressly otherwise provided in the Agreement, any reference to “**writing**” or “**written**” does not (unless specifically provided for in the Agreement) include e-mail;
  - (viii) a reference to any other document is a reference to that other document as amended, varied, novated or supplemented (other than in breach of the provisions of this Agreement) from time to time; and

- (ix) any phrase introduced by the terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.61 The headings in this Agreement are inserted for ease of reference only and will not affect the interpretation or construction of this Agreement.

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1.62 In the event of any inconsistencies between the terms of this Agreement and the Exhibits hereto, the terms of this Agreement shall prevail.

## 2 License

2.1 AEZS hereby grants to CH the exclusive right to use the Licensed Rights and any Improvements during the Term to Commercialise, including marketing, selling and offering to sell, of the Licensed Product in the Field in the Territory and to conduct the necessary actions to obtain and maintain Marketing Authorisations in the Field in the Territory (the “License”). The License includes the right to make or have made the Licensed Product provided that CH shall not exercise such right unless AEZS fails to or is unable to supply the Licensed Product to CH in accordance with the terms set out in the Supply Agreement or the Supply Agreement terminates (other than where this Agreement also terminates) or expires and is not renewed. AEZS is entitled to perform the PCT in the Territory and furthermore reserves all rights not expressly granted herein and/or in the Supply Agreement, in particular to use the Licensed Rights and any Improvements outside the Territory for any purpose. AEZS shall remain entitled to use the Licensed Rights and Improvements for each and any development purposes.

2.2 CH may grant sublicenses (which may include the grant of distribution rights) in respect of the Licensed Rights and any Improvements to Third Parties. To the extent CH grants sublicenses hereunder, CH shall impose obligations on the sublicensee which are consistent with the obligations imposed on CH under this Agreement and shall ensure that the sublicensee meets all reporting, accounting and confidentiality obligations set forth herein. CH shall promptly inform AEZS upon conclusion of a sublicense agreement regarding the Licensed Rights.

2.3 AEZS shall ensure that CH is offered the opportunity to bid to acquire the exclusive right to Commercialise the Licensed Product for therapeutic indications in the Territory on the same basis as any other potential licensees.

AEZS shall notify CH in writing of the commencement of an out-licensing process for any therapeutic indication(s) of the Licensed Product in the Territory and shall promptly make available to CH all relevant information in its possession

- (i) relating to the manufacture, development, and use of the Licensed Product for the relevant therapeutic indication which has not previously been provided to CH through the JSC, to enable CH to evaluate whether it wishes to submit a bid as part of the relevant licensing process.

- (ii) If, within [Redacted] after being notified about the commencement of an out-licensing process, CH chooses to submit a bid to acquire the right to Commercialise the relevant therapeutic indication(s) of the Licensed Product in the Territory, the Parties shall enter into good faith negotiations to discuss and agree the terms of the exclusive licence. During this time AEZS shall neither be prevented from negotiating a license with potential other licensees nor shall it in general be obliged to accept any bid submitted by CH to acquire the right to Commercialise a therapeutic indication(s) of the Licensed Product.

- (iii) Notwithstanding the foregoing, AEZS shall not grant to any third party the right to Commercialise a therapeutic indication of the Licensed Product on worse terms than those last offered by CH to AZES for the relevant therapeutic indication. However, AEZS shall not be obliged to disclose any terms offered by any third party but shall provide a statement addressed to CH and certified as true and accurate by the managing Director of AEZS confirming that the terms agreed with the third party are not worse than the terms last offered by CH for the relevant therapeutic indication.

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## 3 Delivery of Licensed Know-how/ Promotional Materials

Promptly after the Effective Date, but not later than end of [Redacted], AEZS shall disclose and supply to CH a data package that shall include all Licensed Know How and a copy (in electronic format, where possible) of all promotional materials, including sales representative training materials, sales literature and brochures, if any, used by AEZS to promote the Licensed Product. CH shall have the right (and to permit its sub-licensees and contractors) to use, copy, modify and amend the Licensed Know-How and any such promotional materials for the purpose of promoting, distributing and selling the Licensed Product in the Territory. The foregoing obligations shall apply equally to all Promotional Materials, including sales representative training materials, sales literature and brochures, used by AEZS's other licensees to promote the Licensed Product to the extent that AEZS is not prevented from disclosing and/or granting CH the foregoing rights under its agreements with those other licensees.

#### 4 Regulatory

4.1 AEZS hereby transfers to CH all existing Regulatory Approvals and any applications in progress at the Effective Date relating to the Licensed Product in the Territory ("**Existing Regulatory Approvals**"), all of which are set out in Exhibit 1.18. CH accepts this transfer.

4.2 AEZS shall promptly, but not later than end of [Redacted], take all necessary steps to perform the transfer of the Existing Regulatory Approvals to CH and CH shall reimburse AEZS for any external costs actually and reasonably incurred by AEZS in taking such steps. AEZS shall:

- (i) deliver all duly signed forms, documents or irrevocable consents (as the case requires) for the transfer, assignment and registration of each of the Existing Regulatory Approvals to or in the name of CH; and
- (ii) execute and deliver all necessary documents and take such further steps as may reasonably be required by CH to ensure the orderly transfer of the Existing Regulatory Approvals from AEZS to CH.

CH shall provide AEZS at CH's costs all assistance which AEZS reasonably requires to give effect to this Section 4.2.

4.3 AEZS will provide reasonable support, information, explanations and assistance to CH:

- (i) in order to promptly (but not later than end of [Redacted]) effect the transfer the Existing Regulatory Approvals to CH;
- (ii) to enable CH to maintain any Existing Regulatory Approvals; and
- (iii) to enable CH to apply for the Paediatric Use indication for the Licensed Product (after successful finalisation of the PCT). Such support shall include providing a full clinical data package to enable CH to make such an application, and any data required to satisfy any required post-marketing commitments.

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4.4 AEZS shall:

- (i) until the completion of the re-registration of the Marketing Authorisations in the name of CH (or as it directs), comply timeously with all Applicable Laws or orders imposed by any competent Regulatory Authority having jurisdiction over such Marketing Authorisations; and
- (ii) initiate, perform, carry out and/or complete, as the case requires, without undue delay after prior consultation with CH and in line with CH's reasonable instructions, (a) all reasonable commitments and undertakings given to, or imposed by, the competent Regulatory Authorities prior to the Effective Date or to the satisfaction of the Regulatory Authorities and (b) until completion of the (re-) registration of the relevant Marketing Authorisation in the name of CH, all other regulatory activities which are necessary to properly obtain or maintain or vary or amend any of the Marketing Authorisations. CH shall reimburse AEZS for any external costs actually and reasonably incurred by AEZS in performing the activities referred to at (b) above.

4.5 AEZS shall perform the PCT in the Territory, make all relevant applications and filings and communicate with the competent Regulatory Authorities. Any data resulting from the PCT shall be regularly shared with CH and may be used and shared by AEZS for and with its cooperation partners, including any existing and future licensees outside of the Territory.

- 4.6 CH shall be responsible, at its own costs, for and own Regulatory Approvals and applications for the Licensed Product in the Territory. Upon completion of the registration of the relevant Marketing Authorisations in the name of CH according to Section 4.2, CH shall be solely responsible for Marketing Authorisations and their submission, maintenance, defense and renewal, as the case may be. CH shall use Commercially Reasonable Efforts to obtain any further Regulatory Approvals for the Licensed Product required or commercially desirable in each country of the Territory. AEZS shall support this by fulfilling its obligations under this Agreement.
- 4.7 For the avoidance of doubt, CH shall be responsible, at its own costs, for all necessary pricing and reimbursement applications, negotiations with competent authorities, and approvals on a country by country basis. CH shall use its Commercially Reasonable Efforts to negotiate a high Pricing and Reimbursement Approval.
- 4.8 CH acknowledges that the PCT is a multinational study and extends to the Territory. CH shall provide all reasonable support to AEZS as requested by AEZS for the conduct of the PCT, including the provision of all available and relevant data controlled by CH.
- 4.9 CH shall co-operate with AEZS and any responsible Third Party as indicated by AEZS for Regulatory Approvals for territories outside the Territory.

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## 5 Steering Committee

- 5.1 The Steering Committee oversees the Development and Commercialising of the Licensed Product in the Territory and the success of the collaboration between AEZS and CH, and provides a forum for communication and consultation between the Parties. The tasks of the Steering Committee include:

- (i) regularly informing CH about the status of and consulting with CH in relation to progress with the PCT and related activities, and keeping CH (a) informed about all commercial activities in other territories outside of the Territory about which AEZS has information, and (b) fully appraised of any ongoing development of the Licensed Product or any therapeutic product containing the same active ingredient as the Licensed Product; in each case provided that this information can be shared by AEZS with CH without infringing any confidentiality obligation in existence as at the Effective Date. Where AEZS is under a confidentiality obligation as at the Effective Date which would prevent it sharing the relevant information with CH it will seek consent from the relevant third party to share such information with CH (it being acknowledged that whilst AEZS will use all reasonable endeavours to persuade the relevant third party to give such consent, this cannot be guaranteed);
- (ii) regularly providing AEZS with information and an overview of the Commercialisation of the Licensed Product in the Territory including the status of pricing and reimbursement negotiations and approvals on a country and country basis;
- (iii) regularly exchanging a copy (in electronic format, where possible) of all promotional materials, including sales representative training materials, sales literature and brochures, used by AEZS or by or on behalf of CH to promote the Licensed Product;
- (iv) reporting on progress against the Business Plan;
- (v) reviewing time frames for the completion of the PCT and for submission of applications for and status of Regulatory Approvals etc.; and
- (vi) coordinating patents and other IPR applications regarding Joint Inventions and/or improvements.

- 5.2 The Steering Committee may establish sub-committees, which, e. g., are responsible for Commercialisation and for co-ordination of Regulatory activities (each of which would be chaired by CH), and for the Development, for IPR and/or for the supply of Licensed Product (each of which would be chaired by AEZS).

- 5.3 The Steering Committee consists of an equal number (up to three (3) per Party) of representatives of AEZS and representatives of CH. The representatives in the Steering Committee are to have the necessary experience, expertise and seniority in order to address all strategic questions, which the Steering Committee is to deal in accordance with Section 5.1. Each Party may invite

guests to the meetings, in order to discuss special technical or commercial topics. A chairman for each meeting of the Steering Committee shall be appointed on an alternate basis, whereby AEZS designates the chairman for the first meeting, the chairman for the second meeting shall be designated by CH, and chairman for each subsequent meeting shall alternate between the Parties. A secretary of the Steering Committee shall be appointed on an alternate basis, whereby CH designates the secretary for the first meeting, the secretary for the second meeting shall be designated by AEZS, and the secretary for each subsequent meeting shall alternate between the Parties. The secretary is responsible for scheduling the quarterly meetings, the distribution of documents before the meetings and the minutes of the meetings. Each Party shall have the right to call for an extraordinary meeting. The Party, on whose request the extraordinary meeting is being held, will send relevant information and an agenda for such meeting to the other Party and to each member of the Steering Committee.

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5.4 The Steering Committee meets for the first time as soon as reasonable after the Effective Date (but not later than January 2021) and afterwards as needed, in order to fulfil its tasks, however, at least calendar-quarterly. The meetings of the Steering Committee may take place by teleconference, videoconference or face-to-face, whereby at least two (2) meetings per year ideally should take place face-to-face. Each Party may call for an extraordinary meeting of the Steering Committee up to two (2) times per calendar year with fifteen (15) days advance notice. The meeting place alternates between the company seats of the Parties, unless they agree otherwise. Each Party bears its own cost in connection with the work of the Steering Committee.

5.5 All decisions of the Steering Committee are to be made in good faith and in the best interest of the Agreement, shall be reflected in the minutes of the relevant meeting and the Parties shall use their reasonable efforts to take decisions unanimously. In the event that the Steering Committee is unable to agree on any matter after good faith attempts to resolve such disagreement in a commercially reasonable fashion, then either Party may refer the disagreement to a personal face-to-face meeting between the Chief Executive Officer of AEZS (or another appropriate representative of AEZS) and the Chief Executive Officer of CH (or another appropriate representative of CH) which meeting shall take place within fourteen (14) days of the date of the relevant referral. If these persons are not able to resolve such disagreement in a mutually acceptable manner within a further fourteen (14) days after such face-to-face meeting, then: (i) for or in respect of any decisions which relate to the IPR or the Development of the Licensed Product (including conducting the PCT) or matters outside of the Territory, the vote of AEZS with appropriate consideration of the interests of CH shall be decisive; and (ii) for decisions on all other matters (including for or in respect of the Commercialisation and/or the Regulatory Approval procedures in respect of the Licensed Product in the Territory), the vote of CH with appropriate consideration of the interests of AEZS shall be decisive. The decisive vote of AEZS or CH (as the case may be) may not lead to a financial burden of CH or AEZS respectively or amend or conflict with any of the express terms of or override the rights of the Parties pursuant to this Agreement. It is acknowledged that any decision of the JSC (including any decisive vote of CH pursuant to this Section) in relation to a change of the Business Plan shall not be deemed to reduce CH's obligations under Section 14.1.

## 6 Business Plan

6.1 CH shall promptly following the Effective Date, but at the latest [Redacted] thereafter, prepare and deliver to AEZS a Business Plan setting out in more detail, inter alia, CH's planned promotional and marketing activities in the Territory for the first [Redacted] following the Effective Date. CH's activities described in the Business Plan will comply with the efforts and resources consistent with commercially reasonable practices of a company in the pharmaceutical industry with similar resources as CH with respect to the commercialisation of a pharmaceutical product at a similar stage of research, development or commercialization, taking into account relevant factors including, without limitation, measures of patent coverage, relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of such product, the regulatory structure involved, the market potential of such product, pricing and reimbursement status, and profitability of such product, and other relevant factors, including comparative technical, legal, financial, commercial, scientific and/or medical factors.

6.2 CH will present an update to the Business Plan to AEZS (via the Steering Committee) annually, or more frequently in the case of material change, for review and discussion between the Parties.

## 7 Commercial Supply

Subject to CH obtaining and maintaining the necessary Marketing Authorisations for the Licensed Product in the Territory, AEZS will supply CH with the Licensed Product in accordance with a separate supply agreement (“**Supply Agreement**”) and a quality agreement (“**Quality Agreement**”) to be agreed upon between the Parties.

## 8 Pharmacovigilance

Within [Redacted] after the Effective Date, AEZS and CH shall agree upon safety data exchange procedures in a separate and detailed safety agreement (“Pharmacovigilance Agreement”).

## 9 Names and Trademarks

CH shall be responsible for branding of the Licensed Product. CH is aware that AEZS is the owner of the registered trademarks listed in Exhibit 1.35. However, these registered trademarks are not approved by EMA for use together with the Licensed Product within the Member States of the European Union. AEZS does grant to CH the right to (i) use (and grant sub-licenses of the right to use, on the same conditions as set out in Section 2.2) the unregistered and registered trade marks and logos set out in Exhibit 1.35 for the purpose of Commercialising the Licensed Product in the Field in the Territory; and (ii) cross-refer to any trade marks for the Licensed Products which are registered and used outside of the Territory in regulatory and marketing documentation relating to the Commercialisation of the Licensed Products in the Field and in the Territory, always provided that such use and cross-reference is in line with regulatory requirements. AEZS shall not be liable for any third party claim resulting from such use by CH.

## 10 Payments

10.1 For the rights licensed hereunder, CH shall pay to AEZS, within thirty (30) days after the Effective Date, a non-refundable and non-creditable upfront fee in the amount of Euro 1,000,000.00 (one million).

10.2 In addition to the upfront fee under Section 10.1, CH shall pay to AEZS the following one-time, non-refundable and non-creditable milestone payments:

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### 10.2.1 Regulatory Milestones

Receipt of the first Pricing and Reimbursement Approval for the Licensed Product in France: if the Pricing and Reimbursement Approval is > Euro 300 per test, Euro 200,000 (€ two hundred thousand) or if the Pricing and Reimbursement Approval is between [Redacted], Euro 100,000 (€ one hundred thousand);

Receipt of the first Pricing and Reimbursement Approval in Germany: if the Pricing and Reimbursement Approval is > Euro 300 per test, Euro 200,000 (€ two hundred thousand) or if the Pricing and Reimbursement Approval is between [Redacted], Euro 100,000 (€ one hundred thousand);

Receipt of the first Pricing and Reimbursement Approval in Italy: if the Pricing and Reimbursement Approval is [Redacted], Euro 200,000 (€ two hundred thousand) or if the Pricing and Reimbursement Approval is between [Redacted], Euro 100,000 (€ one hundred thousand);

Receipt of the first Pricing and Reimbursement Approval in Spain: if the Pricing and Reimbursement Approval is [Redacted], Euro 200,000 (€ two hundred thousand), or if the Pricing and Reimbursement Approval is between [Redacted], Euro 100,000 (€ one hundred thousand);

Receipt of the first Pricing and Reimbursement Approval in the United Kingdom: if the Pricing and Reimbursement Approval is [Redacted], Euro 200,000 (€ two hundred thousand) or if the Pricing and Reimbursement Approval is between [Redacted], Euro 100,000 (€ one hundred thousand);

(vi) Grant of the first Marketing Authorisation from the European Commission for the Licensed Product for Paediatric Use: Euro 500.000 (€ five hundred thousand); and

(vii) Achievement of a mean average reimbursement price for the Licensed Product of [Redacted] across [Redacted]: Euro 500.000 (€ five hundred thousand).

#### 10.2.2 Commercial Milestones:

- (i) Upon annual Net Sales first reaching Euro 4,000,000 (four million): Euro 250,000 (€ two hundred fifty thousand);
- (ii) Upon annual Net Sales first reaching Euro 6,000,000 (six million): Euro 400,000 (€ four hundred thousand);
- (iii) Upon annual Net Sales first reaching Euro 8,000,000 (eight million): Euro 600,000 (€ six hundred thousand); and
- (iv) Upon completion of annual Net Sales first reaching Euro 10,000,000 (ten million): Euro 1,000,000 (€ one million).

10.3 The regulatory milestone payments are payable within thirty (30) days after the respective milestone was achieved. The commercial milestone payments are payable within thirty (30) days after the end of the calendar year in which the respective milestone was achieved.

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10.4 For the rights licensed hereunder, CH shall pay to AEZS a license fee, the amount of which depends upon the total annual Net Sales in the respective calendar year during the Term of this Agreement (“**License Fee**”):

<u>Net Sales</u>	<u>License Fee</u>
up to Euro 2,000,000.00 (€ two million)	10,0 %
between Euro 2,000,000.00 (two million) and Euro 3,000,000.00 (three million)	12,5 %
between Euro 3,000,000.00 (three million) and Euro 4,000,000.00 (four million)	15,0 %
above Euro 4,000,000.00 (four million)	20,0 %

By way of illustrative example only, if CH achieved annual Net Sales of €6,000,000 (six million Euros), the License Fee to be paid by CH to AEZS would be calculated as follows:

$$\begin{aligned} & (10\% \text{ of } \text{€}2,000,000) + (12.5\% \text{ of } \text{€}1,000,000) + (15\% \text{ of } \text{€}1,000,000) + (20\% \text{ of } \text{€}2,000,000) \\ & = \text{€}200,000 + \text{€}125,000 + \text{€}150,000 + \text{€}200,000 \\ & = \text{€}675,000 \end{aligned}$$

If and when, on a Licensed Product by Licensed Product basis and country by country basis, the Generic Competition in the relevant country in the Territory:

- (i) achieves up to [Redacted] market share by volume (calculated on number of units sold), the License Fees payable for the Net Sales in such country set forth in this Section 10.4 shall be paid without any reduction;
- (ii) achieves more than [Redacted] market share but less than 50% (fifty percent) market share by volume (calculated on number of units sold), the License Fees payable for the Net Sales in such country set forth in this Section 10.4 shall for so long as the market share continues at that level be reduced by 25% (twenty five percent);
- (iii) achieves more than [Redacted] market share but less than 75% (seventy five percent) market share by volume (calculated on number of units sold), the License Fees payable for the Net Sales in such country set forth in this Section 10.4 shall for so long as the market share continues at that level be reduced to 50% (fifty percent); or

(iv) achieves more than [Redacted] market share by volume (calculated on number of units sold), the License Fees payable for the Net Sales in such country set forth in this Section 10.4 shall be reduced to 15% (fifteen percent).

10.5 CH shall pay AEZS a royalty of ten percent (10%) of Sublicense Income during the respective Term. CH shall pay these royalties to AEZS within thirty (30) days of each calendar year in which the relevant Sublicense Income is received by CH for a Licensed Product.

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## 11 Payment Terms

11.1 All payments are to be made in Euro and are exclusive of the applicable VAT. Payments and applicable VAT are payable to the account of AEZS at:

BANK: [Redacted]  
IBAN: [Redacted]  
BIC: [Redacted]  
stating a reference for payment.

11.2 Of all payments to be made under Section 10 CH may retain taxes and other duties payable under the tax laws of Ireland and may forward such retained payments to the competent tax authorities only if the following conditions are met:

- (i) the respective tax is an income tax and not use tax, franchise tax, sales tax or other tax;
- (ii) AEZS is the debtor of such income taxes under applicable laws;
- (iii) CH is required by applicable laws to retain the tax from AEZS and to forward such tax to the competent tax authorities; and
- (iv) CH issues a correct application for grant of a waiver (*Freistellungsbescheinigung*) (or equivalent, if applicable) for License Fees and other payments.

All other taxes and duties payable by CH shall be paid by CH.

11.3 The License Fees based on sales under Section 10.4 are payable within thirty (30) days after the end of each quarter of the year to which they correspond. At the time of payment, CH will make available to AEZS a report accounting for all Net Sales and for all payments from sublicensee.

11.4 CH is only permitted to set off payments to be made under Section 10 against potential claims against AEZS, if such claims against AEZS are either admitted or adjudicated.

11.5 Any late payment shall bear interest in the amount of seven percent (7%) per annum above the base rate from time to time of the Bank of England.

11.6 CH shall account for all data which may be necessary to prove the correctness and completeness of its payments. AEZS is entitled, after reasonable prior notice, to have an independent auditor inspect CH's books once every calendar year at CH's regular business hours. CH shall pay the costs of the auditor if the report of CH and the calculation of the auditor reveals a difference of five percent (5 %) or more to the disadvantage of AEZS. Any underpayments are immediately payable.

11.7 License Fees based on payments made in other currencies than Euro shall be calculated at the exchange rate of the European Central Bank published in the afternoon of the last business day in the respective accounting period (e. g., <http://www.ecb.int>).

## 12 Intellectual Property Rights

- 12.1 Each Party shall remain owner of its own IPR existing prior to the Effective Date or generated outside of this Agreement.
- 12.2 CH hereby acknowledges that AEZS is the owner of all Improvements developed by AEZS and CH shall acquire no rights, title or interest whatsoever in or to any such Improvements, except as specifically provided herein.
- 12.3 AEZS hereby acknowledges that CH is the owner of all Improvements developed by CH and AEZS shall acquire no rights, title or interest whatsoever in or to any such Improvements, except as specifically provided in the Agreement.
- 12.4 In the event that, during the continuance of this Agreement, CH, its Affiliates or permitted sublicensees develop Improvements with respect to the use of the Licensed Product in the Field, CH shall furnish AEZS with timely written notice of such Improvements, and shall furnish AEZS with a data package which, in CH's reasonable opinion, contains all information, know how and other data in CH's possession as AEZS will require in order to implement such Improvements for the Development, Manufacture, Commercialisation and/or other use of Licensed Product, but subject to and without prejudice to CH's license rights granted by virtue of this Agreement. CH shall, and hereby does, grant AEZS a non-exclusive, sub-licensable, transferable, perpetual, royalty-free license to use and sublicense all Improvements and all information, know how and other data pertaining to all Improvements furnished by CH to AEZS hereunder for the purpose of Developing, Manufacturing, Commercialising and otherwise using the Licensed Products outside the Field and/or outside the Territory. However AEZS shall not have the right to sub-license any Improvements developed by CH or its Affiliates or permitted sub-licensees to any of its other licensees unless that other licensee has agreed to AEZS having the right to license any Improvements developed by that other licensee to CH on the terms contained in Section 12.5.
- 12.5 In the event that, during the continuance of this Agreement, AEZS, its Affiliates or permitted other licensees develop Improvements with respect to the use of the Licensed Product in the Field, and in relation to Improvements developed by AEZS's other licensees, as at the Effective Date AEZS has the right to license these Improvements to CH, AEZS shall furnish CH with timely written notice of such Improvements, and shall furnish CH with a data package which, in AEZS' reasonable opinion, contains all information, know how and other data as CH will require in order to implement such Improvements for the Manufacture, Commercialisation and/or other use of Licensed Product. Except where AEZS has no right to license the relevant Improvements to CH pursuant to a written agreement executed by AEZS prior to the Effective Date, AEZS shall, and hereby does, grant CH an exclusive, sub-licensable, transferable, perpetual license to use and sublicense all information, know how and other data pertaining to all Improvements furnished by AEZS to CH hereunder for the purpose of Manufacturing, Commercialising and otherwise using the Licensed Products in the Field within the Territory. Following the Effective Date AEZS shall use Commercially Reasonable Efforts to agree with potential future licensees on clauses that allow the licensing of Improvements generated by such licensees to CH.
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- 12.6 In the event the Parties have jointly developed or reduced to practice patentable inventions as a result of the work performed under this Agreement (“**Joint Inventions**”), the Parties shall jointly own such Joint Inventions. AEZS shall timely and fully assume any Joint Inventions of its employees in accordance with the German Act on Employee Inventions (*Arbeitnehmererfindungsgesetz*) or respective foreign laws. Joint Inventions will be filed for patent protection in the name of both Parties. The Parties will decide on a case-by-case basis which Party will have the responsibility for handling the filing, prosecution and maintenance of any Joint Inventions. Unless agreed otherwise, the Parties will equally share the costs of filing, prosecution and maintenance of Joint Patent Rights. Any employee invention compensation shall be borne by the respective employer. AEZS is entitled to use the Joint Patent Rights on an exclusive, cost free basis (i) outside of the Field and (ii) outside of the Territory inside the Field, and to grant licenses to Third Parties within such scope. CH is entitled to use the Joint Patent Rights on an exclusive, cost free basis within the Field and within the Territory and to grant sublicenses to Third Parties in accordance with Section 2.2 above.
- 12.7 AEZS shall be responsible for prosecuting the applications regarding Licensed Patent Rights without undue delay and in a competent manner and shall maintain the Licensed Patent Rights during the Term. AEZS will take all measures which are necessary for the protection of the Licensed Patent Rights. AEZS shall keep CH reasonably informed of any material issues relating to the prosecution and maintenance of the Licensed Patent Rights and shall provide to CH copies of all material correspondence with the relevant patent offices in respect of the Licensed Patent Rights. AEZS shall consult with CH in respect of, and CH shall have the right to advise and comment upon, the prosecution of patent application claims that are subject to CH’s licence rights under this Agreement in the Territory. AEZS shall, in good faith, consider such advice and comments of CH but shall not be obliged to accept and realize such advice and/or comments. All costs related to the prosecution and maintenance of the Licensed Patent Rights shall be borne by AEZS. AEZS shall further pay all expenses regarding the Licensed Patent Rights and shall comply with all formalities which are necessary for the prosecution and maintenance of the Licensed Patent Rights during the Term. In the event a Licensed Patent Right is challenged during the Term by a Third Party, AEZS shall be in charge of the defense of the Licensed Patent Rights.

### **13 Defense of Licensed Rights against Third Party Infringement**

- 13.1 The Parties shall furnish each other with timely written notice of any and all infringements and other unauthorized uses of the Licensed Rights that come to their attention during the Term.
- 13.2 AEZS shall be responsible for taking all actions, in the courts, administrative agencies or otherwise, including a settlement, to prevent or enjoin any and all such infringements and other unauthorized uses of the Licensed Rights in the Territory and in the Field, and CH shall take no action with respect to any such infringement or unauthorized use of Licensed Rights, without the prior written authorisation of AEZS; provided, however, that CH shall provide at the request and cost of AEZS such assistance as AEZS shall reasonably request in connection with any action to prevent or enjoin any such infringement or unauthorized use of any of the Licensed Rights. In the event AEZS is unable or unwilling to sue the alleged infringer within (i) [Redacted] of the date of notice of such infringement; or (ii) [Redacted] before the time limit, if any, set forth in the applicable laws in regulations for the filing of such actions, whichever comes first or in the event CH requires immediate injunctive relieve for breach of its exclusive license and AEZS, after being informed by CH of the breach and the proposed action, is unable or unwilling to take such immediate action, CH may, but shall not be required to take such action as CH may deem appropriate to prevent or enjoin the alleged infringement or threatened infringement of a Licensed Right. In such event, CH shall act at its own expense, and AEZS shall cooperate reasonably with CH at the expense of CH, and AEZS agrees to be named as a nominal Party. In the event of such action by CH, any recovery obtained shall be paid to CH.

## 14 Obligation to Exploit, Non-compete

14.1 CH shall exploit the Licensed Rights and use Commercially Reasonable Efforts to Commercialise the Licensed Products. The obligation to exploit the License includes the performance of suitable and reasonable marketing measures including advertising in applicable publications and the exhibition of the Licensed Products at the relevant fairs in the Territory in regular intervals. CH shall be obliged to agree with its Affiliates and sublicensees using the Licensed Rights on the same exploitation obligation as set forth in this Section 14.1.

If AEZS reasonably believes that CH is not using Commercially Reasonable Efforts with respect to the Commercialisation of the Licensed Product, then AEZS may provide to CH written notice specifying in reasonable detail the reasons for such assertion. Upon receipt of such notice, CH shall have a period of sixty (60) days to justify to AEZS that CH has been using commercially reasonable efforts with respect to Licensed Products or if CH accepts AEZS's assertion, in whole or in part, the Parties shall discuss and use all reasonable efforts to agree how such lack of diligence may be cured and CH shall thereafter have a period of [Redacted] (or such longer period as agreed to by the Parties), to cure the lack of diligence ("**Evidence and Cure Periods**"). If following CH's justification AEZS accepts that CH has used Commercially Reasonable Efforts with respect to the Commercialisation of the Licensed Products, or if the lack of diligence has been cured by CH, then AEZS' notice shall be deemed withdrawn and of no effect. If, within such periods, AEZS does not accept CH's justification and/or CH has not cured such lack of diligence within such period, AEZS shall have the right to refer the issue for decision as set forth below:

The issue shall as a first step be referred in writing by AEZS to the Chairman of CH for resolution and discussion with the Chairman of AEZS. In such case, the Chairmen shall, by phone or in-person, commence discussing the issue in good faith within fifteen (15) days following AEZS's referral. If the Chairmen have not reached a mutually acceptable resolution to the issue within thirty (30) days after receipt of the referral notice, AEZS shall be entitled by serving written notice on CH to seek dispute resolution in accordance with the process set out below.

Each Party is entitled to propose one (1) independent expert within sixty (60) days after written notice by AEZS that it is seeking dispute resolution and the other Party shall not unreasonably withhold its consent to the appointment of such expert, provided that the expert has the appropriate professional, technical, scientific and legal qualifications to undertake the role assigned to it under this process. The Parties shall agree the same set of documents to be made available in English to both experts, which document set will include (i) a detailed written statement prepared by each Party setting out its position on the relevant issues and including any proposals that Party may have for resolution of the relevant issue; and (ii) each Party's response to the other Party's written statement. Both experts will, if they deem appropriate, be entitled to seek clarification from the Parties as to any of the statements or proposals made by either Party in their written statement or responses and each Party will on request make available all information in its possession and shall give such assistance to both experts as may be reasonably necessary to permit them to make their determinations. Both experts shall provide their expert opinion in English language within three (3) months, or longer if reasonably necessary, after the second expert has been appointed.

If the two (2) experts are unable to come to a joint opinion and the Parties are unable to solve the dispute among themselves within a further sixty (60) day period after both experts have provided their expert opinions, as soon as possible thereafter a third expert who is an expert appropriate professional, technical, scientific and legal qualifications and who shall act as an expert and not an arbitrator shall be appointed jointly by the Parties. Such third expert shall have access to the written opinions of the two other experts as well as to all documents which were made available to the two previous experts, and shall be entitled to receive on request copies of any relevant information and documentation in the possession of either of the Parties.

Within sixty (60) days, or longer if reasonably necessary, after the third expert has been appointed, such third expert shall approve either one of the two written opinions of the first two experts, or shall come to his own independent opinion. If the opinion is acceptable to both Parties it shall be considered final and binding on the Parties. However if either Party objects to the opinion then the opinion shall not be considered final or binding, and the Parties may revert to their respective remedies under this Agreement. AEZS shall bear the costs of all experts appointed pursuant to the foregoing process.

If following this process it is determined that CH has used Commercially Reasonable Efforts with respect to the Commercialisation of the Licensed Products, and such determination is accepted by both Parties, then AEZS' notice shall be deemed withdrawn and of no effect. If, following this process, it is determined that CH has not used Commercially Reasonable Efforts with respect to the Commercialisation of the Licensed Products or that the lack of diligence has not been cured by CH, and such determination is accepted by both Parties, CH shall have a further period of [Redacted] (or such longer period as agreed to by the Parties), to cure the lack of diligence, failing which AEZS shall be entitled to terminate this Agreement.

- 14.2 AEZS hereby reserves the right to Develop, manufacture, promote, market, distribute and sell, or appoint any Third Party to promote, market, distribute and sell, the Licensed Product in any territory other than the Territory. CH shall refrain, and shall cause any of its Affiliates or sublicensees to refrain, from making Active Sales to customers for the Licensed Product outside the Territory. CH will not establish or maintain a warehouse or marketing facility for the purpose of Commercialising the Licensed Product outside Territory. However, as required by law, nothing in this Agreement shall prohibit either Party making Passive Sales to any customer located within the European Union or European Economic Area.
- 14.3 CH is not permitted to develop, manufacture and commercialise products which compete with the Licensed Product if the development, manufacture, commercialisation and sale of such competing products occurs by using the Licensed Rights or AEZS' Confidential Information. Irrespective of the above, CH is not restricted:
- (i) to use its owned technology if it does not use any of the Licensed Rights and/or Confidential Information of AEZS; or
  - (ii) to perform research and development work if the technologies and/or product resulting from such research and development work do not require the use of the Licensed Rights and/or AEZS' Confidential Information.
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## 15 Warranties

### 15.1 AEZS warrants and represents that as of the Effective Date:

- (i) it complies with all Applicable Laws;
  - (ii) it owns and/or controls the entire rights, title and interest in the Licensed Rights;
  - (iii) it has the right to enter into this Agreement and to grant the licenses contained herein, and has obtained all consents or approvals required from any third parties in relation thereto (however, this does not imply a warranty beyond Section 15.1 (iv) that the Licensed Rights and/or the Licensed Products are free from Third Party rights);
  - (iv) it has no present knowledge from which it can be inferred that the Licensed Patent Rights are invalid or that their exercise would infringe patent rights of a Third Party;
  - (v) it has no present knowledge from which it can be inferred that any Marketing Authorisation will be varied, suspended, revoked, withdrawn or cancelled or otherwise declared invalid by any competent regulatory authority in the Territory;
  - (vi) all information relating to the Licensed Product, the Licensed Rights and the Existing Regulatory Approvals and other matters contained in the virtual dataroom made available by AEZS to CH prior to the Effective Date was at the time true, accurate and not misleading and to the best knowledge of AEZS, having made reasonable enquiries, the virtual data room contains all material information in the possession of AEZS and/or its Affiliates;
  - (vii) no unfulfilled commitments or undertakings have been given to any Regulatory Authority in respect of the Existing Regulatory Approvals and/or the Licensed Products in the Territory other than those set out in Exhibit 15.1 (vii) and it has no present knowledge of any requirement to amend or vary the Existing Regulatory Approvals, other than consequent upon the transfer of those to CH pursuant to Section 4.2;
  - (viii) the Existing Regulatory Approvals set out in Exhibit 1.18 constitute all the Marketing Authorisations granted to or applied by AEZS in the Territory with regard to the Licensed Product and as at the Effective Date, it has fully and timeously complied with all obligations of the holder of the Existing Regulatory Approvals;
  - (ix) (a) AEZS has complied with its obligations under the CNRS Agreement; (b) AEZS has not received any notice from any of the parties to the CNRS Agreement alleging that AEZS has breached any of its obligations under that Agreement and purporting to terminate the CNRS Agreement; and (c) it has no present knowledge of any grounds which would entitle those parties to serve such a termination notice.
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15.2 AEZS makes no representation or warranty and disclaims any guarantee that the Development of the Licensed Product will be successful in whole or in part or that the Licensed Rights or Existing Regulatory Approvals will be suitable for Commercialisation. AEZS expressly disclaims any warranties and conditions, expressed or implied, with respect to the Licensed Rights, including without limitation, patentability any warranty of merchantability or fitness for a particular purpose. Without prejudice to the generality of the foregoing, this exclusion or waiver shall apply in particular to the following information communicated, whether orally or in writing to CH or any of their directors, officers, employees, advisers and representatives, provided that any such statements have not been provided fraudulently, negligently or without due care and attention to their accuracy:

- (i) any projection, forecast, or other forward looking statement relating to the Licensed Product;
- (ii) subject to the warranty and representation in Section 15.1 (vi), the completeness of any information regarding the Licensed Product;
- (iii) any freedom of Third Party rights, any success, profitability or value of any Asset and the commercial marketability or competitiveness of the Licensed Product in the market or its eligibility for reimbursement or any continuation of the price reimbursement by any relevant social security institution, competent regulatory body, public funds, statutory health insurance, agency, legislative body, commission, official or other instrumentality;
- (iv) the extent, duration and validity of any Marketing Authorisation, e. g. that any Marketing Authorisation will not be varied, suspended, revoked, withdrawn or cancelled or otherwise declared invalid by any competent regulatory authority in the Territory;
- (v) any expectation or statement that any pending application for a Marketing Authorisation will be granted;
- (vi) the quality, safety or efficacy of the Licensed Product and other characteristics of the Licensed Product;
- (vii) the presence or absence of any future deficiency letters;
- (viii) the presence or absence of any hearing, investigation or inspection of any regulatory authority alleging any potential or actual non-compliance by AEZS under any applicable law or a lack of safety; and
- (ix) the consequences of the application of the Licensed Product in consumers, patients or participants of clinical trials and the like.

15.3 AEZS undertakes to CH that during the term of this Agreement it shall:

- (i) comply with all Applicable Laws;
- (ii) comply with and perform all of its obligations under the CNRS Agreement; and
- (iii) as soon as reasonably possible following the Effective Date, obtain [Redacted].

15.4 CH warrants and represents that it has the right to enter into this Agreement.

15.5 CH undertakes to AEZS that during the Term of this Agreement it and its Affiliates, sublicensees, distributors and subcontractors will (a) comply with all Applicable Laws relating to the Commercialisation of the Licensed Product and (b) subject to completion of the re-registrations referred to in Section 4.2, hold all Regulatory Approvals, licenses, permits, and similar governmental authorisations necessary or required for them Commercialize the Licensed Product, each in the Field in Territory.

15.6 Except for those representations and warranties set forth in this Section 15, the Parties make no representations or warranties, whether written or oral, express or implied, with respect to the Licensed Product, the Licensed Rights, or the Existing Regulatory Approvals or Commercialisation of the Licensed Product. All other representations and warranties, whether express or implied, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose and non-infringement, are hereby disclaimed by both Parties.

## **16 Liability, Indemnification and Insurance**

16.1 The total aggregate liability and indemnification obligation under or in connection with this Agreement (i) of AEZS to CH for any loss or damage resulting from third party IP infringements shall be limited to and in no circumstances shall exceed [Redacted]; (ii) of each Party under or in connection with this Agreement (whether in contract or for negligence or breach of statutory duty or otherwise howsoever but other than under 16.1 (i) above) to the other Party for any loss or damage of whatsoever nature and howsoever caused, shall be limited to and in no circumstances shall exceed [Redacted].

16.2 Each Party acknowledges and agrees that the other Party's ability to comply with its obligations under this Agreement is dependent upon the first Party performing its obligations under this Agreement, fully and in a timely manner. Neither Party will hold the other Party liable for any material breach of any of its obligations under this Agreement if and to the extent that such breach is a direct result of or directly related to a failure by the first Party to perform its obligations under this Agreement fully and in a timely manner.

16.3 Neither Party shall be liable for any special, incidental, exemplary or consequential damages of any kind (including lost profits) regardless of the form of action, whether in contract, tort, negligence, breach of statutory duty, or otherwise, suffered by the other Party, even if that Party has been informed of the possibility of any such damages in advance. However nothing in this Agreement excludes liability for death or personal injury caused by negligence, or for fraud or gross negligence or wilful misconduct or any liability to the extent the same may not be excluded or limited as a matter of law.

16.4 AEZS shall indemnify CH against any Third Party claims, actions, liabilities, costs and reasonable expenses arising from or related to:

- (i) any breach of any of AEZS's representations, warranties or covenants set forth in this Agreement;
- (ii) any other negligent, wilful or intentionally wrongful act, error or omission on the part of AEZS or any employee, agent or representative of AEZS;
- (iii) any claim by any Third Party for death or personal injury which relates to or has arisen as a result of an inherent defect in the Licensed Product as at the Effective Date; or
- (iv) any claim or proceeding made, brought or threatened against CH by any Third Party that the use by CH of all or any part of the Licensed Product and/or the Licensed Rights in compliance with this Agreement infringes the IPR of that Third Party or of another person.



16.5 AEZS's indemnification obligation under Section 16.4 shall be subject to the following conditions:

- (i) CH shall furnish AEZS with written notice of any such claim or liability within thirty (30) days of the date, on which CH receives notice thereof;
- (ii) AEZS shall be solely responsible for the defense, settlement and discharge of such claims and liabilities; and
- (iii) CH shall, at the reasonable expense of AEZS, furnish AEZS with all assistance reasonably requested by AEZS in connection with the defense settlement and discharge of such claims and liabilities.

CH's failure to comply with its obligations under this Section 16.5 shall not constitute a breach of this Agreement or relieve AEZS of its indemnification obligations pursuant to Section 16.4, except to the extent, if any, that AEZS's defense of the claim or liability was materially impaired thereby.

16.6 AEZS's obligations under Section 16.4 hereof shall not apply to any claims by any Third Party for death or personal injury or allegations for infringement of the IPR of a Third Party to the extent that the claim arises as a result of:

- (i) CH's violation of the terms of this Agreement;
- (ii) CH's use of the Licensed Product and/or Licensed Rights in violation of the terms and conditions of this Agreement;
- (iii) any modification, adaptation or new application of the Licensed Rights made by CH without the prior authorisation of AEZS;
- (iv) any combination of the Licensed Product with any other products;
- (v) defective manufacturing of the Licensed Products by AEZS which shall be handled under the Supply Agreement; or
- (vi) CH's handling, storage, commercialization, promotion or distribution of the Licensed Products which shall be handled under the Supply Agreement.

16.7 CH shall indemnify AEZS against any Third Party claims, actions, liabilities, costs and reasonable expenses arising from or related to:

- (i) any allegation that commercialisation of any of the Licensed Products fail to conform to requirements of any applicable laws and/or any applicable regulatory approvals, including the failure of CH to obtain the necessary Regulatory Approvals;
- (ii) any breach of any of CH's representations, warranties or covenants set forth in this Agreement; and/or
- (iii) any other negligent, wilful or intentionally wrongful act, error or omission on the part of CH or any employee, agent or representative of CH,

provided that CH shall have no obligation to indemnify AEZS to the extent any claim arises out of or results from:

- a) AEZS' or its directors, employees and/or officers' negligence, recklessness or wilful misconduct whether in Manufacturing, testing, storing, or handling of the Licensed Products (unless in compliance with CH's instructions) or otherwise with respect to a breach of its or their obligations under this Agreement or the Supply Agreement;
- b) a defective Licensed Product supplied by or on behalf of AEZS pursuant to the Supply Agreement; or
- c) an inherent defect in the Licensed Product as at the Effective Date.

Section 16.6 shall apply mutatis mutandis to CH's indemnification obligation.

16.8 CH shall maintain, during the term of this Agreement and for the term of any permitted use of the Licensed Rights after termination of this Agreement, general commercial liability insurance with an adequate coverage.

## 17 Term and Termination

17.1 This Agreement shall enter into effect on the Effective Date and shall remain in full force and effect (i) as long as the Licensed Product is covered by a Valid Claim in any country of the Territory; (ii) the expiration of any regulatory marketing exclusivity period or other statutory designation that provides similar exclusivity for the Commercialisation of the Licensed Product in any country of the Territory; or (iii) on a country by country of the Territory, and Licensed Product by Licensed Product basis, for a period of ten (10) years after the First Commercial Sale Date in the respective country of the Territory, whichever term is longer ("**Term**").

17.2 In the event that either Party („**Breaching Party**") commits a material breach or default of any of its obligations hereunder, the other Party hereto (the „**Non-Breaching Party**") may give the Breaching Party written notice of such material breach or default, and shall request that such material breach or default be cured as soon as reasonably practicable. In the event that the Breaching Party fails to cure such breach or default within thirty (30) days after the date of the Non-breaching Party's notice thereof, the Non-Breaching Party may terminate this Agreement as a whole or for certain countries in the Territory or certain fields of use within the Field by giving written notice to the Breaching Party. Termination of this Agreement in accordance with this Section 17.2 shall not affect or impair the Non-Breaching Party's right to pursue any legal remedy, including, but not limited to, the right to recover damages, for any harm suffered or incurred by the Non-Breaching Party as a result of such breach or default.

17.3 A material breach of CH which entitles AEZS to terminate this Agreement for cause in accordance with Section 17.2 shall include, but not be limited to:

- (i) a breach of the obligation to exploit the License in accordance with Section 14.1 above;
- (ii) a default of CH to make payments of License Fees; and/or
- (iii) an attack by CH against the Licensed Patent Rights.

- 17.4 A material breach of AEZS which entitles CH to terminate this Agreement for cause in accordance with Section 17.2 shall include, but not be limited to:
- (i) a breach of AEZS's obligations to conduct the PCT in accordance with Applicable Laws and/or to provide a copy of all relevant data generated in the course of the PCT to CH promptly in accordance with Section 4.3;
  - (ii) a failure to maintain all Licensed Patent Rights pursuant to Section 12.7 or otherwise to comply with the terms of the CNRS Agreement which might have an impact on this Agreement;
  - (iii) termination of the Supply Agreement by CH for AEZS's material breach; or
  - (iv) a failure to transfer the Existing Regulatory Approvals to CH pursuant to Section 4.2.
- 17.5 Each Party shall be entitled to terminate this Agreement if the other Party passes a resolution for its winding-up, or enters into any form of insolvency proceedings including but not limited to if a court of competent jurisdiction makes an order for that Party's winding-up or dissolution, or makes an administration order (or equivalent) in relation to that Party, or if the Party appoints a receiver over, or an encumbrancer takes possession of or sells an asset of, that Party, or makes an arrangement or composition with its creditors generally, or makes an application to a court of competent jurisdiction for protection from its creditors generally.

## **18 Consequences of termination**

- 18.1 In the event of a termination by AEZS in accordance with Sections 17.2 or 17.5 above, the rights licensed to CH shall automatically revert to AEZS.
- 18.2 Upon termination of this Agreement, AEZS shall have the right to retain any sums already paid by CH hereunder, and CH shall pay all sums accrued hereunder which are then due.
- 18.3 Immediately upon termination of this Agreement by AEZS in accordance with Section 17.2 or 17.5, CH shall cease all distribution, marketing and sale of the Licensed Product under the licenses granted hereunder; provided, however, that, if this Agreement is terminated for any reason other than a breach or default hereunder by CH or if this Agreement is terminated after the Parties having followed the process set out in Section 14.1, CH shall have the right to distribute and sell its existing inventory of the Licensed Product for a period of not more than one hundred and eighty (180) days following the date of termination hereof, subject to CH's continuing obligation to pay royalties with respect to the Net Sales derived from the distribution and sale of such existing inventory of the Licensed Product, in accordance with Section 10.4 hereof.
- 18.4 Termination of this Agreement for any reason whatsoever shall not relieve: (i) CH of its obligation to pay all royalties and other amounts payable to AEZS which have accrued prior to, but remain unpaid as of, the date of expiration or termination hereof, or which accrue thereafter, in accordance with Section 18.3 above; (ii) either Party of its obligation to indemnify the other Party against claims and liabilities, as provided in Section 16 hereof; and (iii) either Party of its obligation to maintain commercial general liability insurance coverage, in accordance with the requirements of Section 16.8 hereof.

- 18.5 Except in the case of termination of this Agreement by CH under Section 17.2 or 17.5, the expiration or termination of this Agreement shall not adversely affect or impair AEZS's right to continue to use any and all Improvements licensed by CH to AEZS under Section 12.4 hereof.
- 18.6 Except as otherwise specifically provided in this Agreement, upon expiration or termination of this Agreement for any reason whatsoever, neither Party shall have any further obligations to the other Party hereunder.
- 18.7 In the event of termination of this Agreement by AEZS pursuant to Section 17.2 or 17.5, AEZS shall have the right to freely to demand from CH the transfer of Regulatory Approvals, certifications, applications and permits relevant for the Licensed Product to AEZS or Third Party named by AEZS within a period of one (1) month after the termination date against payment of all external costs which CH incurred in connection with obtaining the Regulatory Approvals etc. to be transferred. The foregoing right shall, where the termination by AEZS is for a breach of the obligation to exploit the License in accordance with Section 14.1 above where the Parties have followed the process set out in Section 14.1, be subject to AEZS agreeing with CH reasonable compensation for transfer of the Regulatory Approvals.
- 18.8 In the event of termination of this Agreement by AEZS pursuant to Section 17.2 or 17.5, the Product Trademarks of the Licensed Product (if any) in the Territory shall be transferred to AEZS on AEZS's costs. The foregoing right shall, where the termination by AEZS is for a breach of the obligation to exploit the License in accordance with Section 14.1 above where the Parties have followed the process set out in Section 14.1, be subject to AEZS agreeing with CH reasonable compensation for transfer of the relevant product Trademarks.
- 18.9 Where CH terminates this Agreement pursuant to Section 17.2 or 17.5, the License shall continue in full force and effect and AEZS shall, provided it has received the upfront payment due under Section 10.1, continue to perform its obligations under Sections 4.2, 4.3(i) and (ii) and 4.4 (i) to the extent that those obligations have not previously been fulfilled. From the date of such termination CH will pay royalties to AEZS for what would have been the remainder of the Term (had the Agreement not been terminated); in case of a termination in accordance with Section 17.2 at fifty percent (50 %) of the royalty rates other payments set out in Section 10 and in case of a termination in accordance with Section 17.5 at one hundred percent (100 %) of the royalty rates and other payments set out in Section 10, and the provisions set out in Section 10 and 11 shall remain in effect to the extent necessary to give effect to this provision. Where CH terminates under Section 17.5 CH shall be entitled to deduct from such royalties any reasonable costs actually incurred by CH in relation to Commercialisation of the Licensed Product following and as a direct result of the happening of the events referred to in Section 17.5, including any additional costs incurred by CH in performing (or in having third parties perform) activities that would previously have been AEZS's responsibility under this Agreement, and reasonable details of any such deductions shall be included in the royalty reports under Section 11.3.
- 18.10 In the event of a termination by CH in accordance with Section 17.2, the rights to Improvements licensed by CH to AEZS under Section 12.4 shall automatically revert to CH and AEZS shall immediately cease (and shall take all necessary steps to ensure that its sub-licensees immediately cease) using any such Improvements and any generated by CH.
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- 18.11 Upon expiry of the Term, the License shall continue in full force and effect but CH shall have no further obligation to pay any royalties or other sums to AEZS.
- 18.12 Termination of the Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available.
- 18.13 On any termination of this Agreement, the provisions in clauses 1, 10 (for so long as the licence and payment of royalties continues under Section 18.9) and 11 (in respect of any payments due up to the date of termination (i.e. the date on which termination becomes effective) or thereafter under Sections 18.3 and 18.9), 12.1, 12.2, 12.3, 16, and 18 to 22 (inclusive) shall remain in effect.

## **19 Confidentiality**

- 19.1 All Confidential Information disclosed, revealed or otherwise made available by one Party („**Disclosing Party**”) to the other Party („**Receiving Party**”) under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party’s Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party’s Confidential Information available to any Third Party, without the prior written authorisation of the Disclosing Party.
- 19.2 In furtherance of the Receiving Party’s obligations under Section 19.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party’s Confidential Information. Without limiting the generality of this Section 19.2, the Receiving Party shall disclose any of the Disclosing Party’s Confidential Information only to those of its officers, employees, agents, consultants, sublicensees, potential sublicensees and financial investors that have a need to know the Disclosing Party’s Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, agents, consultants, sublicensees, potential sublicensees and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party’s Confidential Information. To the extent employees of the Receiving Party to whom the Confidential Information were disclosed are leaving the Receiving Party; the Receiving Party will ensure that, to the extent legally possible, the Confidential Information is covered by a valid post-contractual confidentiality obligation. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party’s Confidential Information and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party’s Confidential Information.
- 19.3 Each Party will treat the terms of this Agreement in the same manner as Confidential Information which they receive from the other Party. However, CH agrees that AEZS will have to comply with the applicable requirements for SEC-filings.
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19.4 The obligations under Sections 19.1 and 19.2 hereof shall not apply to the extent that the relevant Party can prove by written evidence that the respective Confidential Information:

- (i) passes into the public domain, or becomes generally available to the public through no fault of that Party;
- (ii) was known to it prior to disclosure hereunder by the Disclosing Party;
- (iii) is disclosed, revealed or otherwise made available to it by a Third Party without any obligation of non-disclosure and/or non-use;
- (iv) is required to be disclosed under applicable law or by court order; provided, however, that the relevant Party shall furnish the other Party with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the other Party, in its sole discretion, to take appropriate action in order to prevent its Confidential Information from passing into the public domain or becoming generally available to the public; or
- (v) is independently developed by the relevant Party without breach of this Agreement as evidenced by contemporaneous written records.

19.5 Upon expiration or termination of this Agreement for any reason whatsoever, the Receiving Party shall return to the Disclosing Party, or destroy, as the Disclosing Party shall specify in writing, all copies of all documents and other materials that contain or embody any of the Disclosing Party's Confidential Information, except: (i) to the extent that the Receiving Party is required by applicable law or permitted under this Agreement to retain such documents and materials; or (ii) where the Receiving Party is CH, CH shall be entitled to retain and use the Licensed Know-How in accordance with the terms of this Agreement. Within thirty (30) days after the date of expiration or termination of this Agreement, the Receiving Party shall furnish the Disclosing Party with a written certificate, confirming that the Receiving Party has complied with its obligations under this Section 19.5.

19.6 All of the Receiving Party's obligations under Sections 19.1 and 19.2 hereof, with respect to the protection of the Disclosing Party's Confidential Information, shall survive the expiration or termination of this Agreement for any reason whatsoever.

## **20 Assignment**

20.1 Neither Party may, assign, transfer, novate or otherwise dispose of its rights or obligations under this Agreement, in whole or in part, without the consent of the other Party, except that each Party may assign this Agreement and its rights and obligations hereunder without the consent of the other Party:

- (i) to an Affiliate or as part of an internal reorganisation;
- (ii) in connection with the transfer or sale of all or substantially all of its assets of the business to which this Agreement relates; or
- (c) in connection with its merger, sale of stock, consolidation or similar transaction.

Where CH assigns its rights and obligations under this Agreement to a third party as part of a bona fide transaction of the sort referred to in (ii) and (iii) above it shall pay to AEZS a non-creditable and non-refundable assignment fee of [Redacted] of the price paid to CH as consideration for the relevant assignment, as and when such price is received by CH. CH shall promptly notify AEZS of any assignment pursuant to (ii) or (iii) above and of any sums due to AEZS in connection with such assignment pursuant to this Section.

- 20.2 A Party assigning its rights or obligations under this Agreement shall not be released from its contractual obligations under this Agreement unless the assignee has agreed in writing to the other Party to be bound by all of the terms and provisions of this Agreement.
- 20.3 AEZS shall not be entitled to assign, transfer, novate or otherwise dispose of any of the Licensed Rights, without first obtaining CH's written consent.

## **21 Publications; Press Releases**

Except as may be required by Applicable Laws, including applicable SEC regulations, neither Party will originate any publicity, press or news release, or other public announcement, written or oral, whether to the public press or otherwise, relating to this Agreement without the prior written approval of the other Party, such approval not to be unreasonably withheld. In such event the Party wishing to disclose such information shall provide to the other Party for its prior approval a written copy of such public announcement at least ten (10) business days prior to disclosure. If the other Party does not object to the public announcement within five (5) business days after receipt of the written copy, the public announcement is deemed to be approved.

## **22 General Provisions**

- 22.1 This Agreement shall be governed by and interpreted in accordance with the laws of Germany, without reference to conflict of laws' principles. The United Nations Convention on Contracts for the International Sale of Goods shall not be applicable.
- 22.2 For any dispute relating to the validity, performance, construction or interpretation of this Agreement, exclusive jurisdiction shall vest with the Frankfurt am Main, Germany courts.
- 22.3 The Parties are aware of the risk that one or more terms of this Agreement may be held to be void or invalid contrary to the present expectations of the Parties. In this case, the Parties wish to remove any doubt which may arise concerning the validity of this Agreement. Should one or more terms of this Agreement, including this provision, be or become wholly or partially void or invalid, or should this Agreement contain a gap, the Agreement shall, contrary to Sec. 139 German Civil Code, remain valid not only in case of doubt, but shall always remain valid.
- 22.4 This Agreement, together with all Exhibits attached hereto, constitutes the entire agreement between the Parties, and supersedes all prior oral and written agreements between the Parties with respect to the subject matter hereof. No modification or amendment of this Agreement shall be binding upon the Parties unless in writing; this shall also apply to any waiver of the written form requirement.
- 22.5 Neither Party shall be liable for any failure to perform, or any delay in the performance of, any of its obligations under this Agreement to the extent that such Party's performance is prevented by the occurrence of an event beyond the reasonable control of the Party whose performance is affected thereby (force majeure), including but not limited to war, fire, adverse weather conditions, strike, unavailability of supplies, pandemic or epidemic, acts of terrorism or acts of government agencies. In the event that a Party's performance is affected by the occurrence of any event of force majeure, that Party shall furnish immediate written notice thereof to the other Party hereto.

[Signature page follows]

**Aeterna Zentaris GmbH**

Name: Dr. Klaus Paulini  
Function: Managing Director  
Date:  
Place: Frankfurt am Main

**Aeterna Zentaris GmbH**

Name: Dr. Eckhard G. Guenther;  
Function: Managing Director  
Date:  
Place: Frankfurt am Main

**Consilient Health Ltd.**

Name:  
Function: Managing Director  
Date:  
Place: Dublin

**Exhibits**

Exhibit 1.12: Data Package

Exhibit 1.18: Existing Regulatory Approvals

Exhibit 1.31: Licensed Know How

Exhibit 1.32: Licensed Patent Rights

Exhibit 1.35: Licensed TMs

Exhibit 1.36: Marketing Authorisations

Exhibit 1.45: Product Specification

Exhibit 1.57: List of countries

Exhibit 15.1 (vii): List of Post-marketing commitments and current status as at the Effective Date

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