CHDR

AGREEMENT

The undersigned:

1. The CENTRE FOR HUMAN DRUG RESEARCH, a foundation located in Leiden in the Netherlands having its registered office at Zernikedreef 8, 2333CL LEIDEN, The Netherlands, and in the present matter lawfully represented by its Chief Executive Officer Prof Dr J. Burggraaf and its Chief Scientific Officer Dr Geert Jan Groeneveld (hereinafter referred to as "CHDR"); and

2. ENTHEON BIOMEDICAL CORP having its registered office at 595 Howe Street, 10th floor, Vancouver, British Columbia, Canada, V6C2T5, hereby lawfully represented by its Chief Executive Officer Timothy Ko and its Chief Scientific Officer Dr. Andrew Hegle, (hereinafter referred to as "Client"),

together referred to as "Parties" and individually as a "Party", hereby make this Agreement ("Agreement") dated as of date of last signature (the "Effective Date").

Whereas:

A. The Client is interested in research on a study to explore the safety and efficacy of continuous intravenous infusion of [redacted] (the "Product") in producing smoking cessation in healthy subjects with nicotine addiction; **[Commercially sensitive information redacted.]**

B. CHDR has the facilities and know-how to carry out such research; and

C. Client and CHDR are, in the performance of this Agreement, in compliance with the obligations arising out of the Good Clinical Practice Guidelines and the Dutch Act on Medical-scientific Research Involving Human Subjects.

Agree as follows:

Article 1: Definitions and interpretation

The following terms shall have the meaning ascribed to them below:

"Agreement": means this agreement, together with all Annexes attached hereto.

"Background IP": shall mean any Intellectual Property, other than Foreground IP, already owned by Parties on the Effective Date.

"Clinical Trial": any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. This definition is in line with article 1.12 of the Good Clinical Practice Guidelines.

"Clinical Trial Foreground IP": shall mean an Invention that relates to the Clinical Trial methodology, techniques and technology used by CHDR in the Project.

“Confidential information”: shall mean any information belonging to either Party that is not in the public domain and was disclosed to the other Party for the purposes described in this Agreement, including but not limited to, any Intellectual Property of either Party.

"Effective Date": shall mean the date this Agreement takes effect. The Effective Date is date of last signature.

"Foreground IP": shall mean any Intellectual Property that is conceived, created or developed by either Party, or by a contractor of either Party, in the course of the work conducted under the Project.

“Good Clinical Practice Guidelines”: Good Clinical Practice Guidelines shall mean the E6 (R2) Guideline for Good Clinical Practice of the International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use.

"Intellectual Property (IP)": means any and all intellectual property and rights in or to intellectual property, including (a) any and all trademarks, service marks, brand names, certification marks, trade dress, assumed names, trade names, logos and other indications of origin, sponsorship or affiliation, together with the goodwill associated therewith (whether the foregoing are registered or unregistered); registrations thereof in any jurisdiction and applications to register any of the foregoing in any jurisdiction, and any extension, modification or renewal of any such registration or application; (b) any and all inventions, developments, improvements, discoveries, know how, concepts and ideas, whether patentable or not in any jurisdiction; (c) any and all patents, supplementary protection certificates revalidations, designs, industrial models and utility models, patent applications (including reissues, continuations, divisions, continuations in-part and extensions) and patent disclosures; (d) any and all database rights, design rights, topography rights and registrations thereof; (e) any and all non-public information, trade secrets and proprietary or confidential information and rights in any jurisdiction to limit the use or disclosure thereof by any person; (f) any and all writings and other works, whether copyrighted, copyrightable or not in any jurisdiction, such works including computer programs and software (including source code, object code, data and databases); (g) any and all copyrights, copyright registrations and applications for registration of copyrights in any jurisdiction, and any renewals or extensions thereof; (h) any and all agreements, licenses, immunities, covenants not to sue; and (i) any and all other intellectual property or proprietary rights.

"Product Foreground IP": shall mean an Invention that relates to the Product of the Company in the Project.

“Trial Subjects”: shall mean any individual volunteers who participate in the Project.

Article 2: Scope of the Agreement

2.1 Subject to article 2.2, the Parties hereby agree that CHDR shall conduct a Clinical Trial of the Product (the “Project”) as described in more detail in the proposal protocol entitled: “an investigation of the safety and efficacy of continuous intravenous infusion of [redacted] in producing smoking cessation in healthy subjects with nicotine addiction*”* which is annexed to this Agreement as Annex 1(“the “Protocol”). Subject to article 2.2, the Protocol shall be considered to constitute an integral part of this Agreement and shall establish the means for obtaining insurance coverage for the Project.

[Commercially sensitive information redacted.]

2.2 The provisions of article 2.1 shall only apply on the condition precedent that the Protocol is approved by the Dutch Medical Ethics Review Committee.

2.3 CHDR shall perform the Project in accordance with industry best practices, reasonable care and skill and in compliance with all laws, rules and regulations applicable to the Project.

2.4 If necessary, CHDR will be allowed, after consultation with and the express written approval of Client, to engage the services of third persons or organisations for specific matters relating to the Project, provided that CHDR shall ensure that such third persons and organisations are subject to obligations of confidentiality which are no less strict than the confidentiality obligations of CHDR under this Agreement and the Processor Agreement (as defined below). In as far as these third persons or organisations have access to personal data, CHDR will enter into a data processor agreement with these third persons or organisations as detailed in the processor agreement to be entered into between CHDR and the Client, substantially in the form of Annex 6 hereto (the “Processor Agreement”).

Article 3: Prices and payment

The Parties have agreed on a quotation for the Project as shown in Annex 2 (the “Quotation”). The Parties agree that the Quotation does not include applicable Dutch value added tax. Client shall be invoiced by CHDR according to the Payment Schedule in Annex 3. Any payment owing hereunder shall be made within thirty (30) days after date of invoice. After being invoiced by CHDR, Client shall transfer the amount by the indicated payment date to the bank account indicated on the invoice. The Quotation is agreed upon by the Parties on the basis that Client and CHDR carry out the tasks and activities described in Annex I.

Article 4: Coordination

4.1 Each of the contracting Parties will elect one or more individuals within its organisation who shall be responsible for maintaining contacts on the executive level.

4.2 CHDR elects Dr. Geert Jan Groeneveld, MD, for scientific and medical items, and Prof Dr. J. Burggraaf for financial and contractual items. Client elects Dr. Andrew Hegle for scientific and medical items, and Timothy Ko for financial and contractual items.

Article 5: Intellectual Property

5.1 Client and CHDR understand and agree that this Agreement shall not affect the pre-existing ownership, interests, or rights of either Client or CHDR in any Background IP developed prior to the Effective Date, whether or not used in the course of the Project.

5.2 Any Intellectual Property, conceived, developed, or reduced to practice as a result of the work conducted under the Project (an "Invention") shall be owned or co-owned by the Party or Parties that developed it, unless the Invention is either "Product Foreground IP" or "Clinical Trial Foreground IP".

5.3 The Client shall own all rights, title and interest in and to Product Foreground IP and CHDR shall own all rights, title and interest in and to Clinical Trial Foreground IP.

Article 6: Obligations of Client

6.1 Client shall perform its assigned responsibilities set out in Annex 5 hereto.

6.2 Client undertakes to use reasonable efforts to enable CHDR to carry out the Project, including by, among other things: (a) providing CHDR with all available and relevant information concerning the Product with which the Project is concerned, including, in particular, any information which may be relevant to the safe implementation of the Project; and (b) supplying CHDR with the Product free of charge, within the timeframe and in the quantities set forth in the Protocol.

Article 7: Obligations of CHDR

7.1 CHDR shall perform its assigned responsibilities set out in Annex 5 hereto.

7.2 CHDR shall use its best efforts to complete the Project according to the estimated timelines, as shown in Annex 4.

7.3 CHDR shall immediately inform Client in writing if CHDR becomes aware that circumstances are such that there will be a substantial delay in the progress of the Project. In such an event the Parties shall, by mutual consent, make an arrangement concerning the consequences of the delay on the subsequent implementation of the Project and/or this Agreement.

7.4 CHDR shall give Client's monitoring personnel access to all files which have been collated on any individual Trial Subjects who participate in the Project and shall allow these personnel to make copies of such files, either in whole or in part, but only in as far as the personal data in the files concerned has been made anonymous.

7.5 Subject to article 7.5 below, CHDR shall promptly inform Client in writing of any proposed amendments to the Protocol ("Protocol Amendment") at least ten (10) days prior to implementing any such Protocol Amendment.

7.6 CHDR shall obtain Client's prior written consent prior to implementing any Protocol Amendment that constitutes a material change to the Protocol. The Client shall have the exclusive discretion in determining whether a Protocol Amendment constitutes a material change to the Protocol.

7.7 CHDR shall immediately notify Client if FDA or any other governmental health or regulatory authority provides notice of intent to perform, or without notice commences, an inspection related to or potentially affecting the Project, and shall promptly, upon issuance, provide Client a copy of any correspondence to or from FDA (or any other governmental health or regulatory authority) resulting from any such inspection or relating to the Project or CHDR's ability to perform clinical research.

Article 8: Data analyses and publication

8.1 Subject to the provisions of this article 8, all data, results, analysis conclusions and observations pertaining to the Product and arising from or, generated in the course of the Project (collectively "Data") shall be the sole property of Client. CHDR shall be entitled to use the Data for

publications in, and/or oral presentations to, scientific media and/or forums (collectively "Publications"), with the understanding that CHDR shall not do so unless it has previously informed Client of the proposed Publication and provided such Publication to Client for review and comment not less than thirty (30) days before such proposed use.

8.2 Within ten (10) days of receipt of the Publication referred to article 8.1 above, Client shall advise CHDR in writing of any proprietary or patentable information contained in the Publications and may, as necessary, formally request CHDR to delay disclosure of such Publication on the basis that such postponment is necessary to protect Client's intellectual property rights (and the Parties hereby agree that the protection of intellectual property rights ought weigh the importance of publishing the data). Upon such request CHDR shall postpone the disclosure of such Publication for a period not to exceed ninety days after the Project completion; provided however, if Client notifies CHDR that additional time is required to enable Client to safeguard it intellectual or proprietary property interests, as determined in Client's exclusive discretion, CHDR shall continue to postpone the disclosure of the Publication for a period not to exceed a maximum of 12 months after the Project completion.

8.3 A postponement request shall, in no circumstances, result in the cancellation of any Publication by CHDR. Notwithstanding the foregoing, in all cases, any agreements on Publications need to comply with the "Revised CCMO Directive on the Assessment of Clinical Trial Agreements" dated 30 August 2011".

8.4 Unless otherwise agreed to by Client in writing, CHDR will not disclose Client's Confidential Information in any proposed Publication in accordance with article 16, Confidentiality and Data Privacy.

8.5 While the Parties acknowledge that a joint Publication is preferred, the authorship of any Publication arising from the Project shall reflect the contribution of individual employees of the Client and CHDR in accordance with prevailing academic standards.

Article 9: Reporting

9.1 CHDR will provide written progress reports ("Progress Reports") to Client for all Trial Subjects participating in the Project on a quarterly basis, and as may be periodically requested by Client, acting reasonably. The content of Progress Reports will include, but not be limited to, the following information: (i) number of Trial Subjects accrued; (ii) number of Trial Subjects withdrawn; (iii) therapy received by each Trial Subject; and (iv) response to therapy for each Trial Subject.

9.2 Unless otherwise agreed by the Parties, after completion of Project or termination of this Agreement, whichever occurs first, CHDR shall provide to Client a draft report of the results and work performed under the Project (the "Draft Report") for Client's review and comment. Client shall provide its comment on the Draft Report within sixty (60) days of receipt by Client. CHDR shall give reasonable consideration to all requested edits received from Client. If the Agreement

is terminated prior to completion of Project, the Draft Report should include, at minimum, the results of the Project up until the date of termination.

9.3 Unless otherwise agreed by the Parties, within thirty (30) days of receiving Client comments on the Draft Report, CHDR shall prepare and provide to Client a signed copy of the final report (the "Final Study Report" and collectively with the Progress Reports, the "Reports").

9.4 Client's entitlement to the Reports shall not affect CHDR's reproduction rights with regard to the Publications described in article 8 above.

9.5 Client shall have the right to submit the Reports and the Data to any drug regulatory authority in any country whatsoever and to use the Reports and the Data in order to obtain patents or other similar intellectual or proprietary property rights with respect to the Product.

9.6 Client may refer to the Report and the Data in any publication, with the understanding that the interpretations and/or conclusions set out in such publications shall be purely Client's responsibility and cannot be attributed to CHDR, unless CHDR has given its prior written consent to the interpretation(s) or conclusion(s) concerned.

9.7 Client shall have the right, upon reasonable notice and during regular business hours, to audit the CHDR's conduct of the Project.

Article 10: Insurance

In accordance with the Dutch "Medical Research involving Human Subjects Act" and the "Decree containing rules for Compulsory Insurance in Medical-scientific Research involving Human Subjects 2015", CHDR shall insure the Trial Subjects who participate in the Project for the following maximum amounts:

(1) € 650.000,-- (i.e. six hundred and fifty thousand Euro) per claim per subject;
(2) € 5.000.000,-- (i.e. five million Euro) per medical research project;
(3) € 7.500.000,-- (i.e. seven million and five hundred thousand Euro) for the total sum for injuries arising out of all medical research projects per insurance year.

Article 11: Liability

11.1 Subject to article 12 and article 11.2 below, Client is not liable to CHDR for any liability, damages, claims, losses, costs, expenses, judgments or reasonable attorney fees ("Damages") arising out of the participation of any Trial Subject in the Project.

11.2 The exclusion in article 11.1 shall not apply: (i) if and to the extent that any Damages exceed the insurance coverage which CHDR has taken out; (ii) to any Damages that were caused by a "defect", as defined in article 6:186 of the Dutch Civil Code, in the Product which Client provided to CHDR; and (iii) to any Damages that resulted from Client's failure to provide CHDR with complete or accurate information on the Product in accordance with Clients obligations under article 6 hereof.

11.3 Except in situations of intentional damage or gross negligence, CHDR is not liable to Client for any Damages, including, but not limited to, any Damages resulting from Client's use of the Data, delays in the implementation of the Project or the non-completion of the Project.

Article 12: Indemnity

Client agrees to indemnify and hold CHDR, their officers and employees harmless from any liability, loss or damage they may suffer, if and to the extent that such liability, loss or damage exceeds insurance coverage taken out by CHDR, as a result of claims, demands, costs or judgments against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including, but not limited to, the use by Client of the results obtained from the activities performed by CHDR under this Agreement; provided, however, that this indemnity shall not apply to any liability, loss or damage resulting from the: (i) the negligent or willful failure of CHDR to substantially comply with applicable governmental requirements; or (ii) the negligence or willful wrongdoing of any officer, employee or contractor of CHDR.

Article 13: Force Majeure; Continuity

13.1 Neither Party shall be considered in default of the performance of its obligations under this Agreement to the extent that the performance of such obligations is prevented by war, civil disturbance, fire, water damage, floods, sit-ins, lock-outs, pandemics, government measures or any other event, occurrence or condition which is not caused, in whole or in part, by such Party and which is beyond the reasonable control of such Party.

13.2 If any CHDR employee or contractor performing obligations on behalf of CHDR under this Agreement is unable to continue performing such obligations for any reason, including, but not limited to, an illness, CHDR shall find a replacement employee or contractor within thirty (30) days.

Article 14: Duration

14.1 This Agreement comes into force as from the Effective Date mentioned above and will continue for the duration of the Project unless otherwise terminated earlier in accordance with article 15 hereof. The Project shall end in accordance with the agreed timelines, as set out in the Protocol. The Parties agree that if necessary the term of this Agreement may be extended by mutual written agreement of the Parties.

14.2 The Parties explicitly agree that as they have included a Retention Period for any personal data collected during the Project, the data will be retained by CHDR in compliance with the Processor Agreement as detailed in article 16.1 and 16.2 of this Agreement.

Article 15: Termination

15.1 This Agreement may be terminated earlier by either Party in any of the following circumstances:

(a) if the judgement of the competent medical research ethics committee that has assessed the Project is irrevocably revoked;

(b) if a reasonable case can be made for terminating the Project in the interests of the health of the research Trial Subjects;

(c) if it transpires that continuation of the Project cannot serve any scientific purpose, and this is confirmed by the medical research ethics committee that has issued a positive decision on the Project;

(d) if one of the Parties has been declared insolvent or a bankruptcy/winding-up petition has been filed in respect of one of the Parties, or one of the Parties is dissolved as a legal entity;

(e) if CHDR, using all reasonable best efforts, is no longer capable of performing its obligations under this Agreement and no replacement agreeable to both Parties can be found;

(f) if one of the two Parties fails to comply with the obligations arising from this Agreement and, provided compliance is not permanently impossible, this compliance has not taken place within thirty days of the defaulting Party receiving a written request to comply, unless failure to comply is not in reasonable proportion to the premature termination of the Project; and

(g) if circumstances beyond the control of both parties make it unreasonable to require the Project's continuation,

provided however that any such termination made under this article 15.1 shall also comply with the "Revised CCMO Directive on the Assessment of Clinical Trial Agreements" dated 30 August 2011.

15.2 In all cases of termination of this Agreement the Parties shall cooperate in order to ensure: (i) the Trial Subjects' safety; (ii) continue appropriate treatment; (iii) delivery of the Final Study Report; and (iv) compliance with all applicable regulations.

15.3 In the event of earlier termination of this Agreement, not being the result of a material breach of CHDR's obligations under this Agreement, the total sums payable by Client pursuant to this Agreement shall be equitably prorated for actual work performed up to and including the date of termination, including non-cancellable services with sub-contractors or reserved beds for 6 weeks after date of termination.

Article 16: Confidentiality and Data Privacy

16.1. All processing of personal data will be in accordance with the Euorpean General Data Protection Regulation ("***GDPR***"). Client shall act as Controller under the GDPR and CHDR shall act as the Processor on behalf of the Client (as those terms are defined in the GDPR). In connection therewith, Client and CHDR shall enter into the Processor Agreement outlining their respective responsibilities.

16.2. Unless the Parties otherwise agreed in writing, the Processor Agreement shall not be affected by the termination of this Agreement, on any ground whatsoever, and shall continue in duration, force and effect in accordance with its terms.

16.3. As Client is established outside the European Union ("***EU***"), Client will appoint a representative in the EU, in writing.

16.4. Prior to processing any personal data of the Trial Subjects, CHDR shall obtain informed consent from each Trial Subject participating in the Project.

16.5. The Parties agree to adhere to the principles of medical confidentiality in relation to Trial Subjects involved in the Project.

16.6. CHDR shall not be required to disclose personal data (as defined in the GDPR) to the Client unless this is required to satisfy the requirements of the Protocol or for the purpose of adverse event monitoring or adverse event reporting, or in relation to a claim or proceeding brought by the Trial Subject in connection with the Project. The Parties shall not disclose the identity of Trial Subjects to third parties without prior written consent of the Trial Subject, except in accordance with the provisions of the GDPR, or in relation to a claim or proceeding brought by a Trial Subject in connection with the Project.

16.7. CHDR shall retain the personal data collected under the Project, on behalf of the Client, for 25 years after database lock (the "Retention Period"). After the lapse of the Retention Period, CHDR shall anonymize the personal data collected under the Project such that identification of any Trial Subject will no longer be possible.

16.8. CHDR shall process all personal data collected under this Agreement in accordance with: (i) the informed consent of each Trial Subject; and (ii) article 6(1)(a) and (f) and 9(2)(j) of the GDPR.

16.9. As Processor, CHDR shall handle all Trial Subject requests' pertaining to article 15 to 18 and article 20 to 22 of the GDPR. As it is of the utmost importance to retain the Data as a complete dataset for the purpose of pharmacovigilance obligations of the Client as well as to preserve the integrity of the Data for scientific purposes, CHDR agrees to waive the following rights it would otherwise be entitled to under the GDPR:

(a) the right to rectification under article 16 of the GDPR, to the extent that factual errors concerning name and address may be corrected;

(b) the right to erasure under article 17 of the GDPR;

(c) the right to restriction of processing under article 18 of the GDPR;

(d) the right to data portability under article 20 of the GDPR;

(e) the right to data portability under article 21 of the GDPR, and;

(f) the right to not to be subject to automated individual decision-making, including profiling under article 22 of the GDPR.

16.10. CHDR and Client shall ensure that only those of their officers and employees (and in the case of Client those of its affiliates) directly carrying out obligations under this Agreement have access to

the Confidential Information of the other Party. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, except where disclosure is required by a regulatory authority or by law, provided that, where feasible, in any such event, the Party required to make the disclose shall provide the other Party with prior written notice and a reasonable opportunity to seek a protective order and shall furnish only that portion of the Confidential Information that its counsel advises is required to be disclosed by law. Each Party undertakes not to make use of any Confidential Information of the other Party, other than in accordance with this Agreement, without the prior written consent of the other Party.

16.11. The obligations of confidentiality set out in article 16.10 shall not apply to information which:

(a) is or becomes part of the public domain by any other means other than a wrongful act or breach of this Agreement by either Party;

(b) is obtained from a third party without restriction who had the legal right to disclose the information;

(c) is already in a Party's lawful possession prior to the disclosure, without restriction on disclosure, as evidenced by such Party's written records; and

(d) has been independently developed by the receiving Party and is not subject to a duty of confidentiality.

Article 17: Assignment

Without the other Party's written consent, neither Party shall assign the whole or any part of this Agreement or any claim arising from it to any third party; provided, however, that notwithstanding the foregoing, Client may assign all of its rights and obligations hereunder without such consent to an affiliate of Client or to a successor in interest by reason of merger, amalgamation, business combination, consolidation or sale of all or substantially all the assets of Client. Subject to the foregoing, this Agreement shall inure to the benefit of and be binding on the Parties' successors and assigns. Any assignment in violation of the foregoing shall be null and void and wholly invalid, the assignee in any such assignment shall acquire no rights whatsoever, and the non-assigning Party shall not recognize, nor shall it be required to recognize, such assignment.

Article 18: Changes / Waiver

This Agreement or any part hereof can only be amended with the written consent of both Parties. Similarly, no waiver of the provisions of this Agreement shall be valid or binding on either Party unless in writing and signed by both Parties.

Article 19: Applicable law and competent court

19.1 The entire relationship between the Parties and any and all claims and disputes arising out of or in connection with this Agreement (including the Annexes) and all other agreements relating thereto (including the Processor Agreement and any non-contractual claims and disputes) shall be exclusively governed by and construed in accordance with the laws of the Netherlands.

19.2 Any unresolvable disputes regarding or in connection with this Agreement shall be exclusively decided by arbitration. The number of arbitrators shall be three. Each party shall choose one

arbiter, whom together shall appoint the third arbitrators. The seat of arbitration shall be the Netherlands. The governing laws shall be the laws of the Netherlands

Article 20: Miscellaneous

20.1 **Notices.** All notices from one Party to the other will be in writing to the addresses set forth below. Notices shall be sent by overnight courier, certified mail, return receipt requested, or by other means of delivery requiring a written acknowledged receipt. All notices shall be effective upon receipt.

If to CHDR:

Centre for Human Drug Research
Zernikedreef 8, 2333 CL Leiden
The Netherlands
Email: kb@chdr.nl

Attention Prof Dr Jacobus Burggraaf, Chief Executive Officer

If to the CLIENT

Entheon Biomedical Corp.
3694 Marine Ave
Belcarra, BC
V3H 4R8
Email: timothy@entheonbiomedical.com

Attention: Timothy Ko, Chief Executive Officer

20.2 **Independent Contractor.** The business relationship of CHDR to Client is that of an independent contractor and not of a partner, joint venturer, employer, employee or any other kind of relationship.

20.3 **Severability.** In the event that any one or more of the provisions contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect.

Annexes:

Annex 1. Protocol / Synopsis

Annex 2. Quotation

Annex 3. Payment Schedule

Annex 4. Timelines

Annex 5. List of responsibilities

Annex 6. Processor Agreement

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This Agreement is drawn up in duplicate and signed in:

Leiden on 05/OCT/2020 Vancouver on 10/7/2020

"Jacobus Burggraaf"

Centre for Human Drug Research
Prof Dr Jacobus Burggraaf
Chief Executive Officer

"Timothy Ko"

Company : Entheon Biomedical Corp.
Name : Timothy Ko
Function : CEO

"Jan Groeneveld"

Centre for Human Drug Research
Dr Geert Jan Groeneveld
Chief Scientific Officer

Annex 1.

Protocol / Synopsis

Project Description

CHDR2031 Clinical Study Synopsis draft (dated 23 September 2020): An adaptive, randomized, double-blind, placebo-controlled, single ascending dose (SAD) study to evaluate the pharmacodynamics, pharmacokinetics and safety of a target-controlled intravenous infusion of [redacted] in healthy smokers

[Commercially sensitive information redacted.]

Annex 2. Quotation

Cost overview

CHDR
Centre for Human Drug Research

Zernikedreef 8 | 2333 CL LEIDEN |The Netherlands | tel: +3171524 64 00
VAT reg: NL924661781B 01

	Description	Total Costs in Euro	Cost breakdown
	Setup & Close out	€ 67,790	
	Clinical conduct (n=[redacted])	€ 659,316	
	Reporting & Analysis	€ 56,352	
	Total without COVID-19 measures	**€ 783,458**	
	COVID-19 surcharge (n=[redacted])*	€ 143,856	
	Grand Total	**€ 927,314**	

Notes

- this quotation is based on the Clinical study synopsis dated 23 September 2020
- this quotation is valid for three months
- study setup, submission to regulatory authorities, clinical conduct, data management, analysis and full CSR included
- data management in standard CHDR format
- insurance of subjects to be arranged by CHDR
- external monitoring costs not included
- study drug receipt confirmation according to local standard
- sample transports not included
- overhead costs included
- pharmacy drug storage at room temperature
- (pharmacy) audit costs not included
- costs of sample storage from 3 months after last subject visit is € 0.25 per tube per month
- pharmacy import license fee is not included
- QP release costs not included
- serum CRH and cotinine not included - costs to be determined (partner labs)
- EEG, rating scales and LSEQ not included - to be discussed
- [redacted] PK and assay development costs not included - to be discussed

* COVID-19 surcharge: the actual costs (if any) will be determined at the time of the study execution. We will adjust our operations to comply with the measures requested by the Dutch authorities (government, RIVM, IGJ, CCMO).

Client and CHDR acknowledge that the below budget is based on a draft study outline and that the budget will be updated based on the final study design and possible changes in Annex 5. The budget difference will be covered in an amendment to this Agreement.

[Commercially sensitive and confidential information redacted.]

CHDR
Centre for Human Drug Research

	TOTAL UNITS	COST in €	COST PER UNIT/HR/SUBJECT	setup	screening	training	clinical conduct	return	follow up	analysis and reporting	Close out	total
HOUSING/FACILITIES (*)	days/subject											-
# weekdays/subject	2.75	[redacted]	hr	-	[redacted]		[redacted]		[redacted]			[redacted]
# evenings/subject	2.00	[redacted]	hr	-	-	-	[redacted]					[redacted]
# nights/subject	2.00	[redacted]	hr	-	-	-	[redacted]					[redacted]
				-	[redacted]		[redacted]		[redacted]			[redacted]
PERSONNEL	days											-
Research supervision	11.00	[redacted]	hr	[redacted]			[redacted]			[redacted]		[redacted]
Medical Specialist	5.00	[redacted]	hr	[redacted]			[redacted]					[redacted]
Project manager	48.00	[redacted]	hr	[redacted]			[redacted]			[redacted]	[redacted]	[redacted]
Study Administration	21.00	[redacted]	hr	[redacted]	[redacted]		[redacted]		[redacted]		[redacted]	[redacted]
Nursing	34.00	[redacted]	hr		[redacted]		[redacted]		[redacted]			[redacted]
Night nursing	32.00	[redacted]	hr				[redacted]					[redacted]
Medical	23.00	[redacted]	hr	[redacted]	[redacted]		[redacted]		[redacted]			[redacted]
Statistician	11.00	[redacted]	hr	[redacted]						[redacted]		[redacted]
Laboratory Staff	22.25	[redacted]	hr	[redacted]	[redacted]		[redacted]		[redacted]			[redacted]
IT Staff	2.00	[redacted]	hr	[redacted]			[redacted]					[redacted]
Quality assurance officer	1.50	[redacted]	hr	[redacted]			[redacted]					[redacted]
Data programming	14.00	[redacted]	hr				[redacted]			[redacted]		[redacted]
Data management	38.00	[redacted]	hr	[redacted]	[redacted]		[redacted]		[redacted]	[redacted]		[redacted]
				[redacted]	[redacted]		[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
RECRUITMENT	adv/subjects			-	-	-	-	-	-	-	-	-
Advertisement	1.00	[redacted]	study	[redacted]								[redacted]
GP Declaration Fee	48.00	[redacted]	subject	-	[redacted]							[redacted]
Recruiters - healthy volunteers	[redacted]	[redacted]	subject	-	[redacted]							[redacted]
				[redacted]	[redacted]							[redacted]
SUBJECT COSTS	in €/sbj											-
Subject Remuneration	[redacted]	[redacted]	subject	-	-	-	[redacted]					[redacted]
Travel Expenses	[redacted]	[redacted]	subject	-	-	-	[redacted]					[redacted]
	meals/subject			-	-	-	-	-	-	-	-	-
Regular Meals (0=no, 1=yes)	6.00	10.80	subject day	-	-	-	[redacted]					[redacted]
	in Euro€			-	-	-	-	-	-	-	-	-
Insurance	[redacted]	[redacted]		-	-	-	[redacted]					[redacted]
				[redacted]	[redacted]		[redacted]					[redacted]
ETHICAL REVIEW	nr											-
BEBO	1.00	[redacted]		[redacted]								[redacted]
				[redacted]								[redacted]
												-
ARCHIVING	# units											-
Document Archiving	1.00	[redacted]									[redacted]	[redacted]
											[redacted]	[redacted]
	days / subject											-
LABORATORY SUPPLIES	2.75	6.00		-	[redacted]		[redacted]		[redacted]			[redacted]
												-
CLINICAL MATERIALS	2.75	6.00		-	[redacted]		[redacted]		[redacted]			[redacted]
												-
MEASUREMENTS	measurements/subject											-
Routine Lab	5.50	[redacted]			[redacted]		[redacted]		[redacted]			[redacted]
Virology	2.50	[redacted]			[redacted]							[redacted]
In-house assays	measurements/subject											-
Drug Screen (complete)	3.50	[redacted]			[redacted]		[redacted]					[redacted]
Breath Alcohol	3.50	[redacted]			[redacted]		[redacted]					[redacted]
Pregnancy testing (serum)	1.25	[redacted]			[redacted]							[redacted]
Pregnancy testing (urine)	0.50	[redacted]					[redacted]					[redacted]
Dipstick urinalysis	5.50	[redacted]			[redacted]		[redacted]		[redacted]			[redacted]
Serum CRH/CRF (corticotrophine)	14.00	0.00		-	-	-	-	-	-	-	-	-
Serum ACTH	14.00	[redacted]					[redacted]					[redacted]
Serum cortisol	14.00	[redacted]					[redacted]					[redacted]
Serum prolactine	14.00	[redacted]					[redacted]					[redacted]
CSSRS	5.50	[redacted]			[redacted]		[redacted]		[redacted]			[redacted]
				[redacted]	[redacted]		[redacted]		[redacted]			[redacted]
SPECIALIZED PROCEDURES	days/ subject											-
NeuroCart®	2.20	[redacted]	per subj day	-	-	[redacted]	[redacted]					[redacted]
												-
CHDR Cardiology	measurements/subject											-
ECG (confirmed Cardiovascular MD)	10.50	[redacted]	per measurement	-	[redacted]		[redacted]		[redacted]			[redacted]
				-	[redacted]	[redacted]	[redacted]		[redacted]			[redacted]
PHARMACY												-
Pre study organization	units											-
preparation - standard	1.00	[redacted]		[redacted]								[redacted]
pharmaceutical review	1.00	[redacted]		[redacted]								[redacted]
drug accountability per item	5.00	[redacted]		[redacted]								[redacted]
preparation per protocol	10.00	[redacted]		[redacted]								[redacted]
	p/y			-	-	-	-	-	-	-	-	-
Annual fee standard	1.00	[redacted]		[redacted]								[redacted]
Storage and stock keeping	units	0.00		-	-	-	-	-	-	-	-	-
*receipt	5.00	[redacted]					[redacted]					[redacted]
*return	5.00	[redacted]					[redacted]					[redacted]
	# of shelfs	0.00		-	-	-	-	-	-	-	-	-
*storage per shelf (# of shelfs)	1.00	[redacted]					[redacted]					[redacted]
				-	-	-	-	-	-	-	-	-
	in Euro			-	-	-	-	-	-	-	-	-
Repackging & Labeling	[redacted]	[redacted]					[redacted]					[redacted]
Dispensing	units/sbj			-	-	-	-	-	-	-	-	-
*dispensing	1.00	[redacted]					[redacted]					[redacted]
*randomisation	1.00	[redacted]					[redacted]					[redacted]
Preparation	units/sbj			-	-	-	-	-	-	-	-	-
Study medication	1.00	[redacted]					[redacted]					[redacted]
Study monitoring period	units	-		-	-	-	-	-	-	-	-	-
*standard	1.00	[redacted]					[redacted]					[redacted]
	# hours	0.00		-	-	-	-	-	-	-	-	-
*site visit per hour	8.00	[redacted]					[redacted]					[redacted]
Study Closure	units			-	-	-	-	-	-	-	-	-
*study closure	1.00	[redacted]									[redacted]	[redacted]
				[redacted]	[redacted]		[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
OTHER COST ITEMS												-
CSSRS license	[redacted]	[redacted]		-	-	-	[redacted]					[redacted]
				[redacted]	[redacted]		[redacted]		[redacted]			[redacted]
GRAND TOTAL				[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]	783,458

NOTES:
One "day" consists of 8 hours
One evening equals one "day" of 8 hours
One night equals one "day" of 8 hours

# subjects	[redacted]
Screening failure factor	2.5
Drop out factor	1

COVID-19 Surcharge cost overview

CHDR

Zernikedreef 8 | 2333 CL LEIDEN |The Netherlands | tel: +3171524 64 00
VAT reg: NL924661TB01

Study Number	**CHDR2031**				
Number of subjects	[redacted]	**please note that the calculation is per cohort**			
Number of Occasions	**1**				
Number of return visits	**0**				

Costs overview*

	#	cost per unit	Total Costs in Euro
Per subject costs			
Quarantine isolation on arrival to CRU (including extra time inhouse & Staff)	[redacted]	€ [redacted]	€ [redacted]
Covid-19 qPCR	[redacted]	€ [redacted]	€ [redacted]
Subject compensation for the extra day and testing	[redacted]	€ [redacted]	€ [redacted]
	days inhouse		
Per subject day housing surcharge (due to reduction of capacity to 75%)**	**2**	€ [redacted]	€ [redacted]
TOTAL Surcharge per cohort	**€**		**35,964.00**

Notes

*This overview provides cost calculation for one cohort. The surcharge is defined per cohort depending on the relevant regulations and CRU capacity.

**The housing surcharge is based on the reduction of the CRU capacity to 75%. The costs will be invoiced per completed cohort and could be adjusted based on the actual clinical unit capacity.

The actual surcharge costs (if any) will be determined at the time of the Project execution. CHDR will adjust its operations to comply with the measures requested by the Dutch authorities (government, RIVM, IGJ, CCMO). The surcharge costs consist of direct costs related to the regulatory implications, as well as the costs related to the decreased clinical research unit capacity (housing) due to social distancing. The housing surcharge is based on 25% capacity reduction. The costs are to be updated based on the situation (regulatory and capacity related) at the time of the Project execution. The actual costs will be provided for sponsor overview at least 2 weeks (two weeks) before the cohort start (defined as admission of the 1st subject group to the CRU) and invoiced separately after the completion of the applicable cohort.

[Commercially sensitive and confidential information redacted.]

Annex 3. Payment Schedule

Payment schedule - CHDR2031	Description	Euro
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]		
Total		[redacted]
Additional COVID-19 measures costs*		
[redacted]	[redacted]	[redacted]
Grand total		[redacted]
*Will be added if COVID-19 measures are in place during study conduct		

For the avoidance of doubt, in case the Project or any part thereof is concluded before the maximum number of subjects permitted by the Protocol, the Parties agree that the Client shall pay only the pro-rata portion of the applicable budget, including any non-cancellable costs incurred by CHDR in connection with the performance of the Project as required under the Protocol and in accordance with the Quotation, up to such decision, including those with respect to the screening of the subjects, housing costs, staff costs, services performed with sub-contractors and reserved beds for 8 (eight) weeks after date of termination. In such case(s) the Parties agree to amend this Agreement accordingly.

[Commercially sensitive and confidential information redacted.]

Payments to be made to

Centre For Human Drug Research
Rabobank
Rogstraat 2
2224 TW Katwijk
The Netherlands
Swiftcode: Rabobank: RABONL2U
IBAN: NL10RABOO1 91 251 089
Account number: 191251089

Annex 4. Estimated Timelines

Signed Protocol, signed contract, IMPD, IB, Insurance certificate	1 week before submission
Submission to Ethics Committee/Competent Authority (EC/CA)	2 weeks before EC meeting
Expected Approval EC/CA	2 weeks after EC meeting
Delivery drug supplies by Sponsor	2 weeks before dosing
Start Recruitment	days after EC approval
First Subject first visit (FSFV) SAD	TBC
Last subject last visit (LSLV) SAD	TBC
Data base Lock (DBL)	4-6 weeks after LSLV
First draft CSR	4-6 weeks after database lock
Final draft CSR	TBC
Final data transfer	TBC

NB – all above timelines are subject to any EC/CA approval, clinical capacity and Protocol amendments. Furthermore, at the time of signing this Agreement, a global pandemic is in progress involving COVID-19 and therefore the timelines may subject to change according to the measures requested by the Dutch authorities (government, RIVM, IGJ, CCMO) to address the situation at the time of the Project execution.

Annex 5. List of responsibilities

ACTIVITY	Client	CHDR	Third Party
STUDY START UP			
1. Design the Project	X	X	
2. Write the Protocol		X	
3. Review the Protocol	X	X	
4. Prepare CHDR site-specific subject information sheet and informed consent		X	
5. Receipt, storage and accountability of drug supplies		X	
6. Provide labels for PK samples		X	
7. Prepare randomisation code		X	
PROJECT INITIATION			
1. Obtain approval from Ethic Committee BEBO, Assent		X	
2. Collect pre-Project documents		X	
PROJECT CONDUCT			
1. Recruitment and screening of Trial Subjects		X	
2. Execute study procedures		X	
3. Perform Trial Subjects' supervision during Project		X	
4. Perform ongoing procedures described in the Protocol		X	
5. Perform end of study evaluation of Trial Subjects		X	
6. Administration site Project file		X	
7. Serious Adverse Events (SAE) recording		X	
8. Notify SAE to Client		X	
9. Notify SAE to Health Authorities and Ethical Committee		X	
10. Sample handling		X	
11. NeuroCart		X	
12. Monitoring by external Party	X		
DATA MANAGEMENT			
1. Development & design of CHDR database (not CDISC)		X	
2. Data entry (double data entry for CRF)		X	
3. Data QC		X	
4. eCRF data entry		X	
5. Address Client queries		X	

6. Data verification before database lock		X	
7. Database lock		X	
8. Integration of pharmacokinetic ("PK") data or other data in database		X	
PK ASSESSMENT			
1. Organize shipment of PK samples		X	
2. PK sample analysis			X [redacted]
3. Statistical analysis of PK samples		X	
4. Provide pharmacokinetic report		X	
STATISTICAL ANALYSIS			
1. Produce listing of all data		X	
2. Perform PD, PK and safety analysis		X	
3. Produce descriptive statistics tables, graphs and statistical testing and/or estimation		X	
MEDICAL WRITING			
1. Produce integrated Project report		X	
2. Prepare scientific publication (Subject to Article 8 of the Agreement)	X	X	

[Commercially sensitive and confidential information redacted.]

Annex 6

PROCESSOR AGREEMENT

1. Entheon Biomedical Corp, having its registered office at 595 Howe Street, 10th floor in Vancouver, British Columbia, Canada, V6C2T5 lawfully represented in this matter by its Chief Executive Officer Timothy Ko (hereinafter: "**the Controller**"); and

2. Centre for Human Drug Research having its registered office at Zernikedreef 8, 2333CL in Leiden, the Netherlands lawfully represented in this matter by its Chief Executive Officer Prof Dr J. Burggraaf (hereinafter "**the Processor**").

hereinafter also referred to collectively as: "**the Parties**" and individually as "**a Party**";

WHEREAS:

(a) the Processor provides services for the benefit of the Controller, as set out in the Agreement between the Client and CHDR (as defined below);
(b) the services entail the processing of Personal Data, including Data concerning health (as those terms are defined below);
(c) the Processor solely processes the data concerned on the instructions of the Controller and not for its own purposes; and
(d) this Processor Agreement is subject to the General Data Protection Regulation (GDPR) (as defined below).

THE PARTIES DECLARE TO HAVE AGREED TO THE FOLLOWING:

Article 1 Definitions

1.1. In this Processor Agreement the following capitalised terms shall have the following meanings

a. Agreement: the sponsor agreement between Controller and Processor concerning CHDR study number CHDR2031
b. Biometric data: personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data
c. Consent: of the Data Subject means any freely given, specific, informed and unambiguous indication of the Data Subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her, as defined in article 4 of the GDPR;
d. Controller: the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law, as defined in article 4 of the GDPR;
e. Data concerning health: Personal Data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status, as defined in article 4 of the GDPR; ;
f. Data Protection Officer (DPO): a person who advises, informs and reports independently either of the Parties about the protection of Personal Data, who acts in accordance with the articles 37-39 of the GDPR;

g. Data Subject: a natural person;
h. General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.
i. Genetic data: personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, as defined in article 4 of the GDPR;
j. Incident: means either:
    (i) an investigation into or a seizure of Personal Data by government officers or a serious suspicion that this will take place; or
    (ii) a personal data breach within the meaning of article 4(12) GDPR;
k. Personal data breach: a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise processed, as defined in article 4 of the GDPR; ;
l. Personal Data: any information relating to an identified or identifiable Data Subject; an identifiable Data Subject is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person as defined in article 4 of the GDPR;
m. Processing: any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction, as defined in article 4 of the GDPR; ;
n. Processor: a natural or legal person, public authority, agency or other body which processes Personal Data on behalf of the Controller, as defined in article 4 of the GDPR;
o. Study Protocol: the document that describes the objective(s), design, methodology, statistical considerations and organisation of the Study.
p. Study: the clinical study to be conducted by the Processor under the Agreement, defined therein as the “Project”.
q. Sub-Processor: any non-subordinated third party engaged by the Processor in the processing of Personal Data within the scope of the Agreement, other than employees.
r. Third party: a natural or legal person, public authority, agency or body other than the Data Subject, Controller, Processor and persons who, under the direct authority of the Controller or Processor, are authorised to process Personal Data, as defined in article 4 of the GDPR.

1.2. The above-mentioned and other terms shall be interpreted in accordance with the GDPR.

1.3. Wherever this Processor Agreement refers to certain standards, the most recent version of that standard is always referred to. To the extent that the standard concerned is no longer maintained, the most recent version of the logical successor of that standard that represents the state of art in the subject matter of the standard referred to should be read instead.

Article 2. Subject-Matter of this Processor Agreement

2.1. This Processor Agreement concerns the processing of Personal Data by the Processor on the instructions of the Controller within the scope of the performance of the Agreement or Agreements.

2.2. The Parties are entering into this Processor Agreement in order to make use of the Processor's expertise in the areas of processing and securing Personal Data collected in connection with the Agreement. The Processor guarantees that it is properly qualified for this purpose.

2.3. This Processor Agreement forms an inseparable part of the Agreement. To the extent that the provisions of the Processor Agreement are inconsistent with the provisions of the Agreement, the provisions of the Processor Agreement shall prevail.

Article 3. Execution of processing

3.1. The Processor guarantees that he will only process Personal Data for the benefit of the Controller to the extent that:
a.) this is necessary for the performance of the Agreement; or
b.) the Controller has given further written instructions for that purpose.

3.2. Within the scope of the provisions of Article 3.1 under a.), the Processor shall only process the Personal Data in accordance with the Agreement and the Study Protocol that is drawn up in accordance with the Agreement.

3.3. The Processor will only process the types of Personal Data from the Data Subjects participating in the Study, as laid down in the Study Protocol.

3.4. The Processor shall follow all reasonable instructions given by the Controller in connection with the processing of the Personal Data. The Processor shall immediately inform the Controller if the instructions are – in its view - in breach of the applicable legislation relating to Personal Data.

3.5. Without prejudice to the provisions of the first paragraph of this Article 3.1, the Processor shall be allowed to process Personal Data if required to do so by law (including by any court or administrative orders based thereon). In that case the Processor shall inform the Controller, before the processing, of the intended processing and the legal requirement, unless that law or court or administrative orders prohibits the disclosure of such information. The Processor shall enable the Controller, where possible, to raise a defence against this mandatory processing and shall also otherwise restrict the mandatory processing to what is strictly necessary.

3.6. The Processor shall demonstrably process the Personal data in a proper and careful manner and in agreement with its obligations as a Processor under the GDPR and other laws and regulations. Within that scope the Processor shall in any event maintain a record of the processing activities within the meaning of Article 30 GDPR and provide the Controller with a copy of that record at the latter's first request.

3.7. In regard to processing Data concerning health, the Processor guarantees that he will not act in breach of the applicable health legislation.

3.8. Unless the Processor has obtained the Controller's explicit prior written consent, it shall not process Personal Data or arrange for the processing of Personal Data by itself or by third parties in countries outside the European Union ("EU"), unless the Processor is legally obliged so by law. If the latter is the case, the Processor shall inform the Controller of that legal requirement before processing, unless that law prohibits the disclosure of such information. Processing Personal Data or arranging for the processing of Personal Data outside of the EU will take place under the conditions as set out in annex 2 attached hereto.

3.9. The Processor guarantees that its employees, contractors and Sub-Processors involved in the Study have signed non-disclosure agreements and shall allow the Controller to review these non-disclosure agreements at the latter's request.

3.10. Before providing the Controller with a copy of the Study data processed by the Processor, the Processor will pseudonymise the data by removing name and address information of the study subjects.

Article 4. Security of Personal Data and monitoring

4.1. The Processor shall demonstrably take appropriate and effective technical and organisational security measures, which correspond, given the state of the art and the costs involved therein, with the nature of the Personal Data to be processed, in order to protect the Personal Data from loss, unauthorised review, corruption or any form of unlawful processing and also to guarantee the (timely) availability of the data. These security measures include measures that may already have been provided for in the Agreement. The measures shall in any event include:

a.) measures to ensure that only authorised employees, contractors and Sub-Processors have access to the Personal Data for the described purposes;
b.) measures ensuring that the Processor and its employees, contractors and Sub-Processors can only access the Personal Data via registered accounts, with an adequate logging of such accounts, which allow access to only the Personal Data which the person or legal person needs to access;
c.) measures to protect the Personal data from accidental or unlawful destruction, accidental loss or amendment or unauthorised or unlawful storage, processing, access or disclosure;
d.) measures for the purpose of identifying weaknesses in relation to the processing of Personal Data in the systems used to provide services to the Controller;
e.) measures to guarantee the timely availability of the Personal Data;
f.) measures to ensure that the Personal Data are separated in a logical way from the Personal Data the Processor is processing either for itself or on behalf of third parties;

4.2. The Controller shall be entitled to monitor (or arrange for the monitoring of) the compliance with the measures set out above in Articles 4.1 The Processor shall in any event allow the Controller, if so requested by the Controller, to investigate (or arrange for the investigation of) this at least once a year at a time to be determined by mutual agreement between the Parties and, furthermore, whenever the Controller has a reason for doing so, based on information or privacy incidents (or the suspicion that such incidents have occurred). The Processor shall reasonably lend assistance with such an investigation. The Processor shall follow any instructions for the adjustment of its security policies that the Controller may reasonably give following such an investigation, within a reasonable period of time.

4.3. The Parties acknowledge that security requirements keep changing and that effective security requires frequent reviews and the regular improvement of outdated security measures. The Processor shall therefore periodically review the measures as implemented on the basis of this Article 4 and, where necessary, improve the measures in order to keep meeting the obligations of this Article 4. The foregoing shall not affect the Controller's power of instruction to take (or arrange for the taking of) additional measures, if necessary.

Article 5. Monitoring, information duties and incident management

5.1. The Processor shall actively monitor breaches of the security measures and report on any (possible) Personal Data breaches to the Controller in agreement with this Article 5.

5.2. As soon as an Incident occurs, has occurred or could occur, or if such is suspected, the Processor shall be obliged to immediately notify the Controller hereof and to provide the latter on that occasion with all the relevant information about:
1) the nature of the Incident;
2) the Personal data that have or may have been affected;
3) the discovered and probable consequences of the Incident; and
4) the measures taken or to be taken in order to address the Incident or to limit the consequences/damage as much as possible.

5.3. Without prejudice to the other obligations of this Article 5, the Processor shall take the measures it may reasonably be expected to take in order to address the Incident as soon as possible or to limit the further consequences of that Incident as much as possible. The Processor shall consult the Controller without delay in order to make further agreements about this subject.

5.4. The Controller hereby instructs the Processor in advance to investigate an Incident, formulate a correct response and take appropriate follow-up steps with regard to the Incident. If the Dutch Data Protection Authority ("*Autoriteit Persoonsgegevens*") needs to be notified, the Controller will instruct the Processor accordingly. This also applies to the Data Subject as provided in Article 5.7.

5.5. The Processor shall always have written procedures in place which enable him to provide the Controller with an immediate reaction in respect of an Incident and to effectively cooperate with the Controller in order to handle the Incident. The Processor shall provide the Controller with a copy of such procedures, if so requested by the Controller.

5.6. Any notifications pursuant to Article 5.2 shall be immediately directed to the Controller or, if relevant, to the employees of the Controller as identified by the Controller in writing during the term of this Processor Agreement. If the Controller has appointed a Data Protection Officer (DPO), the notifications shall be directed to this DPO.

5.7. The Processor may not provide information about Incidents to Data Subjects or other third parties, except where the Processor has a legal obligation to do so or the Parties have so agreed otherwise.

5.8. If and to the extent that the Parties have agreed that the Processor shall have direct contact with the authorities or other third parties with regard to an Incident, then the Processor shall keep the Controller informed hereof on a continuous basis.

Article 6. Assistance duties

6.1. The GDPR and other (privacy) legislation grant Data Subjects certain rights. The Processor shall assist the Controller, by any means necessary, in complying with all applicable law in connection with such rights.

6.2. The Processor shall forward any complaint by or request from a Data Subject relating to the processing of Personal Data that he has received to the Controller without delay. CHDR will remove any information that can lead to identification of the Data Subject and ensure that the information can be identified only by the study number.

6.3. On the Controller's first request the Processor shall provide the Controller with all the relevant information on the aspects of its processing of the Personal Data, so that the Controller can demonstrate, partly on the basis of that information, that it is complying with the applicable (privacy) legislation.

6.4. On the Controller's first request the Processor shall also lend all the required assistance with the performance of the legal obligations the Controller has under the applicable privacy legislation (such as performing a PIA).

Article 7. Engagement of Sub-Processors

7.1. The Processor shall not outsource its activities that consist of the processing of Personal Data or that require the processing of Personal Data to a Sub-Processor without the Controller's prior written consent. The foregoing shall not apply to the Sub-Processors mentioned in Annex 1 hereto, of which the Controller has ascertained that the processing is within the mandate given to the Processor under this Processor Agreement.

7.2. Where the Controller consents to the engagement of a Sub-Processor, the Processor shall impose obligations on this Sub-Processor that are (at minimum) equal to the Processor's own obligations under the Processor Agreement or the law and which shall fit within the scope of the processing mandate granted to Processor under this Processor Agreement. The Processor shall record these arrangements in writing and shall monitor their compliance by the Sub-Processor. In particular, the Processor shall impose on the Sub-Processor the obligation to implement appropriate technical and organizational measures in such a manner that the processing will meet all obligations under the GDPR. The Processor shall provide the Controller with a copy of the agreement or agreements entered into with the Sub-Processor at the Controller's request.

7.3. The Controller's consent for the outsourcing of work to a Sub-Processor does not alter the fact that the use of Sub-Processors in a non-EU country requires consent in agreement with Article 3.8 of this Processor Agreement.

Article 8. Confidentiality

8.1. The Processor is obliged to keep any Personal Data received from or processed for the Controller confidential.

8.2. Each Party shall keep any information received from the other Party confidential unless
   a. The other Party has given explicit consent in writing,
   b. The information is already public without the interference of the receiving Party,
   c. The receiving Party is legally obliged to provide the information because of a law suit or a legal obligation.

8.3. If article 8.2(c) is applicable, the receiving Party shall inform the other Party of that legal requirement before disclosure such information, unless that law prohibits such disclosure.

Article 9. Liability

9.1. Each Party shall be responsible and liable for his own actions.

9.2. The Controller shall indemnify the Processor and hold the Processor harmless from all claims, actions, rights of third parties and fines and other enforcement actions of any data protection authority which are the immediate consequence of an imputable shortcoming by the Controller and/or his contractors and/or processors in the performance of its obligations under this Processor Agreement and/or any violation of the GDPR by the Controller and/or its contractors and/or processors. The same holds true for any liability coming forth from an action or omission of any Sub-Processor contracted by Processor for the purposes of the execution of the Agreement and/or this Processor Agreement.

9.3. Any restriction of liability shall also cease to apply for the Party concerned in the case of an intentional act or omission or gross negligence on the part of that Party.

9.4. Parties agree that in case of discrepancies pertaining to liability between the Processor Agreement and the Agreement, the Processor Agreement prevails.

Article 11. Term and termination

11.1. This Processor Agreement shall take effect on the date on which it is signed. The Processor Agreement shall end 25 years after database lock in case of an interventional Study and 15 years after database lock in case of an observational Study.

11.2. After it has been signed by both parties, the Processor Agreement shall form an integral and inseparable part of the Agreement. However, termination of the Agreement on any ground whatsoever does not terminate the Processor Agreement, unless the Parties agree otherwise in writing.

11.3. Obligations which, by their very nature, are intended to continue after the termination of this Processor Agreement shall continue to apply after the termination of this Processor Agreement. These provisions for instance include those which ensue from the provisions on confidentiality, liability, dispute resolution and the applicable laws.

11.4. Without prejudice to the provisions on this subject in the Agreement, either Party shall be entitled to suspend the performance of this Processor Agreement relating to it or to dissolve it with immediate effect without the intervention of the court, if:

a.) the other Party is dissolved or ceases to exist otherwise;

b.) the other Party materially fails in the performance of its obligations under this Processor Agreement and that failure has not been remedied within 30 days following written notice of default;

c.) either Party is declared bankrupt or applies for a moratorium.

11.5. The Controller shall be entitled to dissolve (“ontbinden”) this Processor Agreement and the Agreement with immediate effect, if the Processor indicates that it is not able (or no longer able) to comply with the reliability requirements imposed on Personal Data processing in applicable legislation and/or in the case-law.

11.6. Without the Controller’s explicit and written consent, the Processor may not transfer this Processor Agreement and the rights and obligations connected with this Processor Agreement to a third party.

Article 12. Retention period of Personal Data

12.1. The Processor shall not retain the Personal Data any longer than is strictly necessary, subject to the Retention Period (as defined in the Agreement), in any form that can lead to the identification of the Data Subject. The Controller instructs the Processor to anonymize the Personal Data after the Retention Period has lapsed.

12.2. At the choice of the Controller, the Processor shall delete or return all the Personal Data to the Controller after the end of the provision of services relating to processing, and shall delete existing copies unless Union or Dutch law requires storage of the Personal Data, pursuant to article 28(3)(g) of the GDPR, for as far as this is compatible with ICH-GCP and the applicable Dutch legislation pertaining to clinical studies.

Article 13. Intellectual Property Rights

13.1. To the extent that the Personal Data or their collection is protected by an intellectual property right, the Controller grants the Processor consent to use the Personal Data within the scope of the performance of this Processor Agreement, the Agreement and the Study Protocol.

Article 14. Final provisions

14.1. The recitals form an inseparable part of this Processor Agreement.

14.2. If one or more of the provisions of this Processor Agreement are null and void or voidable, the other provisions shall continue in full effect.

14.3. This Processor Agreement can only be changed upon written consent of both Parties.

14.4. The Parties shall endeavor to resolve any conflicts by mutual agreement. This includes the possibility of ending the dispute by means of mediation to be decided by mutual agreement.

14.5. All notices from one Party to the other will be in writing to the address set forth hence after. Notices shall be sent by overnight courier, certified mail, return receipt requested or by other means of a delivery requiring a written acknowledged receipt. All notices shall be effective upon receipt.

Contact details Controller
andrew@entheonbiomedical.com
[Confidential information redacted]

Contact details Processor:
DPO-gegevensbescherming@chdr.nl
[Confidential information redacted]

Article 15 Applicable law and competent court

15.1. This Processor Agreement is exclusively governed and construed in accordance with the laws of the Netherlands.

15.2. Any disputes regarding or in connection with the Processor Agreement shall be exclusively decided by arbitration. The number of arbitrators shall be three. Each party shall choose one arbiter, whom together shall appoint the third arbitrators. The seat of arbitration shall be the Netherland. The governing laws shall be the laws of the Netherlands.

[Signature Page to Follow]

This Processor Agreement is drawn up in duplicate and signed in:

Leiden on 05/OCT 2020 Vancouver on 10/7/2020

"Jacobus Burggraaf"

Centre for Human Drug Research
Prof Dr J. Burggraaf
Chief Executive Officer

"Timothy Ko"

Company : Entheon Biomedical Corp
Name : Timothy Ko
Function : CEO

Annex 1 Sub-Processors

Pharmacy:
Apotheek LUMC
LUMC, L0-P30, Albinusdreef 2, 2333 ZA Leiden, The Netherlands

Safety Laboratory Analysis:
Afdeling Klinische Chemie en Laboratoriumgeneeskunde (AKCL)
LUMC, E2-P, Albinusdreef 2, Leiden, 2333ZA, Netherlands

Bioanalysis, Cytokine analysis and antibody analysis:
Analytical Biochemical Laboratory (ABL)
W.A. Scholtenstraat 7, 9403 AJ Assen, The Netherlands

Annex 2

Checklist for Processing outside of the EU

Introduction

Transfers are not defined in the GDPR. However, article 44 of the GDPR indicates that any transfers to third countries or international organizations may not take place unless the transfer is compliant with chapter V of the GDPR. CHDR interprets transfer as meaning both (1) the act of sending data actively to a party located in another country outside of the EU and (2) entering the data in a system that is hosted in a country outside of the EU. Furthermore, any possibility for processing the Personal Data from a location located outside the EU shall be qualified as transfer.

As indicated in article 3.8 of this Processor Agreement, the Parties will describe in this annex on which ground an international transfer of Personal Data outside of the EU shall take place. Below, three steps have been described. The Parties will have to verify step-by-step whether one of the steps applies.

Please note that the Parties cannot choose on which lawful basis they will transfer the data to a third party in a country outside of the EU. If Step I applies, that will be the basis for the transfer. Only if a step is not applicable, the Partoes may proceed with the following step.

The Parties will then need to indicate on which legal basis the transfers shall be based and will indicate which data shall be transferred to which party and country.

Step I.

Please check and indicate whether the Controller or any third party (including Sub-Processors) to whom the data is sent (hereinafter: “Receiving Party”) is located in a country within the EU. If that is the case, this annex is not applicable. If the Controller is located outside the EU, please verify whether there is an adequacy decision for the country in which the Controller or the third party is located via the following web-link: https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en

On the 1 May 2018, the European Commission had recognized:

- Andorra;
- Argentina;
- Canada (commercial organizations);
- Faroe islands,
- Guernsey;
- Israel;
- Isle of Man;
- Jersey;
- New Zealand;
- Switserland;
- Uruguay;
- And the US (limited to the Privacy Shield framework),

As providing adequate protection.

If there is an adequacy decision, the personal data can be transferred to the third country based on the adequacy decision. It should be underlined that this is **different** for the United States (”US”). The EU-US Privacy Shield requires certification. Whether the party in question has such certification, can be verified via the following website: https://www.privacyshield.gov/

Please indicate under this Step I in the text box below that the processing will take place based on an adequacy decision, if that is the case. In case of a US party, also indicate that the US Party has been certified, if that is the case.

If the Controller or any third party (such as a Sub-Processor) is not certified under the EU-US Privacy Shield, there is no adequacy decision. Please continue to the next step.

Please indicate here whether an Adequacy decision is applicable and for which country: Adequacy decision is applicable: It is applicable for Canada Please indicate here whether the Controller or third Party located in the US has a Privacy Shield certification: ……