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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
September 5, 2019

MATEON THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-21990
(Commission
File Number)

13-3679168
(IRS Employer
Identification No.)

29397 Agoura Road, Suite 107
Agoura Hills, CA 91301
(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code
(650) 635-7000

Not applicable.
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of class	Trading Symbols	Name of each exchange on which registered
N/A		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On September 5, 2019, Mateon Therapeutics, Inc. (the “Company”) through its wholly-owned subsidiary Oncotelic Inc., a Delaware corporation (“Oncotelic”) entered into three related agreements with WideTrial, Inc., a Delaware corporation (“WideTrial”) for an Expanded Access Program to evaluate Oncotelic’s therapeutic product candidate OT-101 for the treatment of pancreatic cancer, as well as data access through license agreements. Each of the agreements is summarized below:

Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access (IPSUA) dated September 5, 2019 between WideTrial and Oncotelic

Under the IPSUA, WideTrial and Oncotelic will collaborate in a U.S. Expanded Access Program for evaluation of Oncotelic’s investigational therapeutic product, OT-101, in pancreatic cancer and other cancers known to overexpress TGF-B2 (the “EAP”). Oncotelic will provide WideTrial with supplies of OT-101 at designated treatment sites, for the sole purpose of supplying the EAP. In consideration of the supply of OT-101, WideTrial will pay Oncotelic a fixed price of \$5,000 per patient, per course of treatment (which may include up to eight (8) cycles of treatment at prescribed dosage rates). WideTrial will then conduct the EAP in accordance with the terms and conditions of the IPUSA, and will provide the data relating to the EPA under Data License 1 Agreement and Data License 2 Agreement (described below).

Agreement for Delivery and Licensed Use of Data Generated from OT-101 U.S. Expanded Access (Data License 1 Agreement) dated September 5, 2019 between WideTrial and Oncotelic

Under Data License 1 Agreement, WideTrial has agreed to license certain clinical data relating to patients treated in the EAP plus some additional safety addendums to Oncotelic (the “Dataset”). Data License 1 Agreement provides Oncotelic with a perpetual and transferable license, with certain partial exclusivities to the Dataset. The license grants Oncotelic the ability to use the Dataset for commercial purposes, subject to applicable law including HIPAA and applicable data privacy laws. In consideration for the license, Oncotelic has agreed to pay WideTrial \$2,500 per patient enrolled in the EAP for the first 150 patients and \$1,500 per patient for all patients enrolled in excess of the first 150 patients. Data License 1 Agreement requires an initial payment to WideTrial of \$30,000 for the first 12 patients upon FDA IND Authorization of the first IND submitted for OT-101; a second payment of \$32,500 upon start of treatment of the sixth patient under the EAP; and subsequent payments if the number of patients exceeds 25, the fee shall be paid for each additional patient within 30 days of start of treatment.

Agreement for Delivery and Licensed Use of WideTrial Bonus Dataset (Data License 2 Agreement) dated September 5, 2019 between WideTrial and Oncotelic

Under Data License 2 Agreement, WideTrial has agreed to license certain clinical data relating to other Early Access Programs conducted for third parties to Oncotelic. As part of its ongoing business, WideTrial expects to generate clinical data from multiple sponsored Expanded Access programs in the future and will retain control over this data, subject to various specific agreements and release dates as may be negotiated between WideTrial and the particular manufacturers from time to time. WideTrial intends to maintain a “Bonus Dataset” that comprises all captured clinical data from its sponsored Expanded Access Programs. Data License 2 Agreement provides for a license of that Bonus Dataset to Oncotelic for its internal research and development purposes, including development of quantitative analysis systems for disease modeling, covariate analysis and biomarker discovery. The license is non-exclusive and is non-transferrable without WideTrial’s consent. Data License 2 Agreement can be terminated by WideTrial if Oncotelic suspends the EPA or breaches Data License 1 Agreement or Data License 2 Agreement, including a failure to pay the required license fees under the Data License 1 Agreement.

References to Agreements.

The descriptions of the IPUSA, the Data 1 License Agreement, and the Data 2 License Agreement do not purport to be complete and are qualified in their entirety by reference to the complete copies of the IPUSA, the Data 1 License Agreement and the Data 2 License Agreement, which are attached as exhibits to this Current Report on Form 8-K, and each of which is incorporated herein by reference.

The agreements have been included to provide investors and stockholders with information regarding their respective terms. Those agreements are not intended to provide any other factual information about the Company. The representations, warranties and covenants contained in those agreements were made only for purposes of those agreements and as of specific dates, were solely for the benefit of the parties to those agreements, may be subject to limitations agreed upon by the contracting parties, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Investors are not third-party beneficiaries under any of the agreements and should not rely on the representations, warranties or covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the Company. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the agreements, which subsequent information may or may not be fully reflected in our public disclosures.

Item 8.01 Other Events.

On September 9, 2019, the Company and WideTrial issued a joint press release announcing the execution of the foregoing agreements, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Forward-Looking Statements

This document contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words “will,” “may,” “would,” “approximate,” “expect,” “intend,” and similar expressions and their variants may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the anticipated timing, parameters or results of the EAP, the quantity or quality of any data information to be derived under the licenses with WideTrial; the Company’s ability to effectively use any data from the EAP or the data licenses to further the development of OT-101 or any product candidate, or the Company’s ability to monetize value from the data it expects to receive under the data license agreements. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors that could cause actual events to differ from expectations, including the risk factors included in the Company’s most recent Annual Report on Form 10-K and other periodic reports filed with the Securities and Exchange Commission. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	<u>Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access (IPSUA) dated September 5, 2019 between WideTrial and Oncotelic</u>
10.2	<u>Agreement for Delivery and Licensed Use of Data Generated from OT-101 U.S. Expanded Access (Data License 1) dated September 5, 2019 between WideTrial and Oncotelic</u>
10.3	<u>Agreement for Delivery and Licensed Use of WideTrial Bonus Dataset (Data License 2 Agreement) dated September 5, 2019 between WideTrial and Oncotelic</u>
99.1	<u>Press Release, dated September 9, 2019.</u>

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 hereunto duly authorized.

Mateon Therapeutics, Inc.

Date: September 10, 2019

/s/ Vuong Trieu
By: Vuong Trieu
Chief Executive Officer

Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access (IPSUA)

between WideTrial and Oncotelic

This Agreement is made and entered into on September 5th, 2019 (the "Effective Date"), by and between WideTrial, Inc., a corporation headquartered at 8 The Green, Suite 8298, Dover, DE 19901 ("WideTrial") (the "Sponsor"), and Oncotelic Inc., headquartered at 29397 Agoura Rd., Ste 107, Agoura Hills, CA 91301 ("Oncotelic") (the "Manufacturer") (each a "Party", collectively "Parties" to this bilateral Agreement).

WHEREAS, Manufacturer, among its other activities, is engaged in the business of developing and manufacturing its investigational therapeutic product, OT-101 ("Investigational Product"), and

WHEREAS, Sponsor and Manufacturer intend to collaborate in a U.S. Expanded Access Program for treatment use of OT-101 for 25 or more patients in pancreatic cancer and other cancers known to overexpress TGF-B2 ("USEAPOT101", "The Expanded Access Program", "The EAP"), and

WHEREAS, Manufacturer wishes to provide delivery of the finished Investigational Product (as defined below) to the Sponsor, at the Sponsor's designated treatment sites, for the sole purpose of supplying the EAP, according to the terms and conditions set forth herein, and

WHEREAS, Sponsor wishes to provide data to Manufacturer relating to the Investigational Product and the EAP according to the terms and conditions set forth in two Data License Agreements.

NOW, THEREFORE, for good and valuable consideration as set forth herein, the Parties agree as follows:

1. Definitions:

- 1.1 "Adverse Event" or "AE" shall mean any undesirable medical occurrence in a Subject under the treatment and which is not necessarily caused by the treatment.
- 1.2 "Applicable Law" means all laws, statutes, ordinances, codes, rules, and regulations that have been enacted by a Regulatory Authority in any jurisdiction relevant to the performance of the EAP and which are in force as of the Effective Date or come into force during the Term, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement, including, with respect to the United States, the Prescription Drug Marketing Act, the Federal Food, Drug and Cosmetics Act of 1938, as amended, the Health Insurance Portability and Accountability Act, the Federal Anti-Kickback Statute, and any applicable regulations relating to sampling practices.
- 1.3 "CRO" means a Contract Research Organization company who provides clinical research services for the EAP to the Sponsor.
- 1.4 "Designated Site" means the specific location for Investigational Product delivery to be indicated by Sponsor to Manufacturer in accordance with section 3.2

- 1.5 “**DSUR**” means Development Safety Update Report that is a required annual filing for FDA authorized clinical program involving Investigational Products.
- 1.6 “**Expanded Access Program**”, or “**EAP**” means an FDA-authorized clinical trial for the treatment use of the Investigational Product in patients who are not candidates to participate in any research trials for the particular Investigational Product.
- 1.7 “**The Indication**” for this Agreement shall generally refer to the indication specified in either of the two Protocols defined in 1.14 and 1.15
- 1.8 “**Instructions for Use**” or “**IFU**” means the Manufacturer instructions on how to use the Investigational Product to be attached hereto in within forthcoming Exhibits.
- 1.9 “**Investigational Product**” means a regulated pharmaceutical or device that is not yet approved for marketing in any population by the governing Agency of the particular country or territory of use and, for this Agreement, shall mean OT-101, a TGF β 2-inhibiting antisense oligonucleotide, which is in active clinical development for use in pancreatic cancer.
- 1.10 “**IRB**” means Institutional Review Board.
- 1.11 “**IRB Application**” means any documents and action required by the IRB to obtain IRB approval.
- 1.12 “**IRB Approval**” means the written approval by the IRB of the Protocol and the EAP in the corresponding Site.
- 1.13 “**Protocol**” means either of two clinical protocols for conduct of the EAP, to be drafted and signed by the Sponsor, to be submitted to FDA and IRBs for authorizations, to be attached hereto within forthcoming Exhibits.
- 1.14 “**Protocol 1**” shall be the clinical protocol used for OT-101 treatment of patients with unresectable, gemcitabine refractory, adenocarcinoma of the pancreas (“**Indication**”).
- 1.15 “**Protocol 2**” shall be the clinical protocol used for OT-101 treatment of patients within a range of unresectable, refractory solid tumor cancers known to overexpress TGF- β 2 – excluding gliomas (AA and GBM and other brain cancers) (“**Indication**,” “**Indications**”).
- 1.16 “**Purpose**” shall have the meaning set forth in Section 2.1.
- 1.17 “**QC**” and “**QA**” shall mean Quality Control and Quality Assurance, respectively and refer to the testing and release specifications of the Investigational Product.

- 1.18 “**Safety Plan**” shall have the meaning set forth in Section 6.
- 1.19 “**Serious Adverse Event**” or “**SAE**” shall have the meaning set forth in Section 6.
- 1.20 “**Subject**” means an individual who consents to participate in the EAP.
- 1.21 “**Territory**” means the United States of America (USA or US).
- 1.22 “**Treatment Course**” or “**Course of Treatment**” means the full duration of treatment, up to eight (8) cycles of 96-hour infusion, as delivered according to the Protocols
- 1.23 “**Treatment Cycle**” means a single administration of the Investigational Treatment as part of a periodic round of drug administration, subject to the Protocol and the patient’s care plan, up to eight (8) cycles.

2 **Subject Matter**

- 2.1 **Purpose.** The Purpose of this agreement is to allow Sponsor to provide treatment with the Investigational Product for Subjects suffering from the Indication in the framework of EAP and subject to the Protocol in the Territory.
- 2.2 **Use of Investigational Product.** Manufacturer grants Sponsor a non-exclusive, non-transferable, and non-sublicensable right to use the Investigational Product in the U.S. during the Term of this Agreement for the Purpose of conducting the EAP subject to the terms of this Agreement.
- 2.3 **No Implied License.** Except for the right granted to Sponsor herein, all right, title and interest in and to the Investigational Product shall remain with Manufacturer, whether developed or conceived prior, during or after the Term of this Agreement. Except as expressly provided in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party’s intellectual property rights, either expressly or by implication, estoppel or otherwise.

3 **Order and Delivery**

- 3.1 Sponsor shall issue a purchase order (“PO”) to Manufacturer for each Subject prior to subject’s beginning of Course of Treatment.
- 3.2 The PO shall include specific details for shipping, including address and contact person, and proposed date of treatment which shall be mutually agreed by the Parties.

- 3.3 Manufacturer will use its reasonable efforts to provide the Investigational Product to the Designated Site within 2 weeks from the date of the PO and before the agreed date of treatment. As early as possible, Manufacture will advise Sponsor of shipping date and expected arrival and will provide Sponsor with tracking details.
- 3.4 It is hereby agreed that the POs shall be submitted electronically in a format to be mutually agreed upon by both parties. Example of format is to be included within forthcoming Exhibits.
- 3.5 It is the responsibility of the Manufacturer to deliver the Investigational Product to the Designated Site undamaged, and all delivery costs including delivery insurance and -if necessary- import customs shall be borne by Manufacturer. Title and risk in the Investigational Product shall pass to Sponsor after acceptance by the Designated Site.

4 Manufacturer Obligations

- 4.1 Quality of Investigational Product. Manufacturer undertakes to supply the Investigational Product in compliance with the quality requirements and in accordance with GMP standards and Applicable Law relating to the supply, delivery manufacturing of the Investigational Product or similar products.
- 4.2 Training. Manufacturer shall be responsible to provide Sponsor with educational material regarding the Investigational Product, including Instructions for Use (IFU) document, as well as training to Sponsor personnel.
- 4.3 Regulatory documents.
 - 4.3.1 Initial Documents Required for the Filing of Investigational New Drug (IND) Application: Manufacturer shall provide Sponsor with the following documents, in order to allow it to facilitate the successful submission of IND for EAP:
 - 4.3.1.1 Investigator's brochure for OT-101
 - 4.3.1.2 Letter of Authorization for WideTrial to cross-refer to the U.S. Manufacturer's commercial IND for OT-101
 - 4.3.1.3 Current drafts of Protocols for any planned or authorized research trials involving OT-101
 - 4.3.1.4 Suggested wording for the EAP informed consent form
 - 4.3.2 Manufacturer shall provide Sponsor with all product documentation and clinical data required to support the EAP's regulatory, clinical and IRB authorizations.
 - 4.3.3 Manufacturer Regulatory Commitments. Manufacturer shall provide Sponsor with new versions of the Investigator's Brochure, once they are issued by Manufacturer. Manufacturer shall notify Sponsor of any Investigational Product withdrawals, recalls or clinical hold letters from the FDA.

5 Covenant of Non-Competition

5.1 Manufacturer covenants that during the duration of this Agreement, neither Manufacturer nor any of its subsidiaries or assignees will engage (either directly or indirectly) any Activated Designated Sites in relation to any OT-101 Expanded Access Program sponsored by any party other than WideTrial, as contemplated by this Agreement. Manufacturer is free to conduct its clinical trials across any sites it so desired so long as it is not engaging these sites for the sole purpose of Expanded Access Program.

5.2 For purposes of above, an Activated Designated Site shall mean a health care provider who has signed WideTrial's EAP Site Agreement for the conduct of WideTrial's US Expanded Access Program for OT-101.

6 Sponsor Obligations

6.1 Sponsor shall be the official sponsor of record of the EAP and will assume all sponsor responsibilities defined in section 21 of the U.S. Code of Federal Regulations and ICH-GCP.

6.2 Regulatory Requirements.

6.2.1 Sponsor shall be responsible for compliance with regulatory requirements pertaining to the following:

6.2.1.1 Filing of Intermediate-Population IND (EAP IND) and all components;

6.2.1.2 Annual FDA Reporting

6.2.1.3 Investigator and site-level agreements

6.2.1.4 IRB submissions and follow-up

6.2.1.5 NIH submission for ClinicalTrials.Gov

6.2.1.6 Site coordination and monitoring

6.2.1.7 Adverse events monitoring and reporting

6.2.1.8 Any misconducts / misuse of the investigational product

6.2.1.9 Return and/or destruction of unused investigational product

6.2.2 Sponsor shall notify Manufacturer of any clinical hold letter from the FDA on the Investigational Product notifications of audits/inspections and audits/inspections reports.

6.3 Use of Investigational Product. The Sponsor undertakes to use the Investigational Product and to cause any third parties acting on its behalf including but not limited to CRO, institution and investigators who will conduct the EAP to use the Investigational Product (i) solely for the Purpose; (ii) in accordance with the terms of the EAP Protocols; (iii) in accordance with the IFU (iv) in accordance with the terms of this Agreement; (v) in strict compliance with Applicable Law. Sponsor is not responsible for any acts of non-compliance on the part of the Manufacturer or its affiliates or agents.

- 6.4 Investigational Product Handling. Sponsor shall be responsible for compliance with Manufacturer's procedures for the storage, handling, delivery methods, and disposition, of the Investigational Product from the time of transfer from Manufacturer to the Designated Site until completion of use of such Investigational Product.
- 6.5 Training. Sponsor undertakes to train the CRO, institution, investigators and any other relevant third party that will use and/or otherwise administrate the Investigational Product and the EAP in accordance with the training given to it by Manufacturer in accordance to section 4.2.
- 6.6 Medical Oversight. Sponsor shall be responsible for medical data review for the purpose of monitoring Subjects' safety and ensuring medical data consistency and integrity. Sponsor shall be responsible for the conduct of the clinical trial per ICH guideline including insuring that investigator is trained in GCP and full complied with GCP guideline.

7 **Safety**

- 7.1 Each Party agrees to immediately inform the other Party of all new known and suspected Serious Adverse Events (SAEs) and suspected, unexpected serious adverse reactions (SUSARs) arising in its ongoing clinical programs for OT-101 human use, in a timeframe and breadth that allows compliant regulatory reporting by each Party under its own IND, as detailed in the forthcoming Safety Plan.
- 7.2 Sponsor shall appoint a medical monitor and arrange additional resources as necessary to meet all requirements for safety event reporting and escalation.
- 7.3 Sponsor shall be responsible for the surveillance, receipt, evaluation, and reporting of Adverse Events in the EAP.
- 7.4 Sponsor shall provide Manufacturer with regular transcripts of its AE log, to be included in Manufacturer's end-of-year compilation and filing of DSUR.
- 7.5 Manufacturer shall provide Sponsor an exact copy of its submitted DSUR, which Sponsor shall submit under its own IND.
- 7.6 Sponsor to provide Manufacturer an exact copy of its submitted DSUR
- 7.7 Sponsor and Manufacturer shall mutually establish and agree upon a Safety Plan, setting forth a process of compliance with Applicable Law and both Parties' obligations related to Adverse Event responsibilities for the Investigational Product as well procedures for sharing information between the Parties regarding Adverse Events. Safety Plan documentation shall be included in forthcoming Exhibits.
- 7.8 Manufacturer shall be responsible for reporting to Sponsor of all safety expedited reports and changes to the benefit-risk analysis arising in other clinical programs of the Investigational Product for the Indication, per timeline agreed in the Safety Plan.
- 7.9 Parties shall (a) notify each other of any safety-related regulatory inquiries, request of information or regulatory communication from FDA relating to the safety of OT-101 and (b) provide copies of the regulatory correspondence within two (2) business days of receipt.

7.10 Each Party agrees to provide support with respect to any actual or potential regulatory action, and will supply all necessary information as is reasonable to resolve the issue.

8 Control

8.1 All key documentation and regulatory filings will be subject to Manufacturer review approval, which approval shall not be unreasonably withheld, unless otherwise subject to legal reporting requirements, in which case such approval is not required.

8.2 EAP Steering Committee.

8.2.1 The Parties desire to establish a joint steering committee (the “EAP Steering Committee”) which shall oversee the Parties’ activities under this Agreement and facilitate communications between the Parties.

8.2.2 The EAP Steering Committee shall consist of at least one appointee from Sponsor, the rest will be appointees of Manufacturer and may include people who are unaffiliated with the Parties (e.g. investigator, bioethicists), at Manufacturer’s sole discretion.

8.2.3 The EAP Steering Committee shall meet (including by teleconference) on a monthly basis, or as agreed by its members.

8.2.4 Day to day operations will be run by Sponsor staff members and agents. Sponsor shall consult with the EAP Steering Committee on key decisions and developments.

9 Representation and Warranties

9.1 Mutual Representations. Each of the Parties represents, warrants and covenants to the other that: (a) it is a corporation duly incorporated, validly existing and in good standing; (b) it has taken all necessary actions on its part to authorize the execution, delivery and performance of the obligations undertaken in this Agreement, and no other corporate actions are necessary with respect thereto; (c) it is not a party to any agreement or understanding and knows of no law or regulation that would prohibit it from entering into and performing this Agreement; (d) when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with this Agreement’s terms;

9.2 Mutual Warranties. Each Party represents and warrants to each other that (a) it will perform its obligations hereunder and will, to the best of its abilities, cause any other third party working on its to perform their obligations in accordance with the terms of this Agreement and the Protocol (b) it complies with and will comply and perform its obligations hereunder in accordance with Applicable Law, industry standards, guidance or industry code of practice, and recognized applicable international and ethical principles including ICH GCP in force from time to time; (c) to the best of its knowledge performance of its obligations hereunder will not infringe or violate the rights of any third party including but not limited to property, contractual, employment, trademark, trade secrets, copyright, patent, proprietary information and non-disclosure rights; (d) it will not enter into any other agreements which would interfere or prevent performance of the obligations described herein. and (e) it is not debarred or, to the best of its knowledge, proposed for debarment under 21 U.S.C. § 335(a), or otherwise subject to any restrictions or sanctions by the United States Food and Drug Administration (a “Debarred Person”) Sponsor undertakes to immediately inform Manufacturer on any Debarred Person according to this section.

10 Confidentiality

- 10.1 All Confidential Information (as hereinafter defined) of the Sponsor, Manufacturer (or other parties whose Confidential Information that either Party has in its possession under obligations of confidentiality) shall be held in trust and strict confidence and, except as may be authorized in writing, shall not be used for any purpose other than for the Purpose of this Agreement and shall not be disclosed to any person, association, company, entity or other organization.
- 10.2 For purposes of this Agreement, “Confidential Information” shall include, without limitation, information of either Party (including information of any affiliate of either Party) that is treated by the Party as confidential or is subject to an obligation of the Party to treat such information as confidential, whether such obligation is contractual or arises by operation of law, including without limitation, this Agreement, the Protocol, Clinical Data and Reports, and deliverables made in connection with this Agreement.

11 Consideration

- 11.1 In consideration for the provision of the Investigational Product, Sponsor shall pay to Manufacturer a fixed price of USD 5000 per patient per Course of Treatment which will include Supply for up to eight (8) cycles of treatment at dosage prescribed in the applicable Protocol.
- 11.2 The payment shall be due within 30 days from the receipt of the Investigational Product at the Designated Site for the patient’s first Treatment Cycle within the Course of Treatment.

12 Market Entrance

- 12.1 In the case of State level market approval of OT-101, either Party has the right to suspend enrollment of new patients in the Expanded Access program in the particular State. In such event, existing EAP participants in the State may complete their Course of Treatment in the EAP, but may -at the discretion of either Party to this Agreement- be denied subsequent Courses of Treatment within the EAP. No provision of this Agreement shall impede the Manufacturer from recovering reimbursement from payers at full market price.

13 **Liability**

- 13.1 The Sponsor shall be liable for the communication, coordination and reporting among all parties involved in the conduct of the EAP.
- 13.2 Sponsor is required to maintain adequate clinical trial insurance for the clinical trials
- 13.3 The Sponsor makes no claims to any party regarding the safety or effectiveness of the Investigational Product, and therefore, with respect to Manufacturer or other parties, assumes no liability for product design.
- 13.4 The Manufacturer shall be liable for the purity, quality, and stability of the Investigational Product that is delivered to the Designated Sites for use in the EAP.
- 13.5 Exclusion of Liability. Subject to the indemnification obligations set forth in Section 13 in no event shall either Party be liable (including without limitation, contract, and tort liability) for any indirect, incidental, punitive, exemplary, special or consequential damages, loss of profit, or costs of substitute services suffered by the other Party or any third party, however caused, regardless of the theory of liability, whether in contract, tort, product liability or otherwise.

14 **Indemnification**

- 14.1 Manufacturer Indemnification: Manufacturer shall hold harmless, indemnify, and defend Sponsor from and against any claim, liability, loss, damage or expense, including, without limitation, reasonable attorneys' fees ("collectively: "Loss"), arising out of any third party claim resulting from the use of the Investigational Product, provided that Manufacturer's obligation to hold harmless, indemnify and defend as aforesaid shall be proportionately reduced and shall not apply to the extent that such Loss is the result of Sponsor act of fraud, negligence or willful misconduct or breach of Applicable Law, and further provided that Manufacturer is notified in writing as soon as practicable under the circumstances of any complaint or claim potentially subject to indemnification and has full control of any disposition or settlement of such claim, and Sponsor and everyone on its behalf has fully cooperated with Manufacturer regarding such disposition or settlement; provided however that Manufacturer shall not dispose or settle any claim admitting liability on the part of Sponsor without its prior consent, which consent shall not be unreasonably withheld.
- 14.2 Sponsor Indemnification. The Sponsor shall hold harmless, indemnify, and defend Manufacturer for any Loss arising out of: (i) Sponsor's own or any of its representatives' or agents' act of fraud, negligence, or willful misconduct, (ii) breach of this Agreement; (iii) failure to conduct the EAP in accordance with the Protocol; (iv) breach of Applicable Law or regulation, provided that Sponsor's obligation to hold harmless, indemnify and defend as aforesaid shall be proportionately reduced and shall not apply to the extent that such Loss is the result of Manufacturer's act of fraud, negligence or willful misconduct or breach of Applicable Law, and further provided that the Sponsor is notified in writing as soon as practicable under the circumstances of any complaint or claim and has full control of any disposition or settlement of such claim, and Manufacturer and everyone on its behalf has fully cooperated with the Sponsor regarding such disposition or settlement; provided however that the Sponsor shall not dispose or settle any claim admitting liability on the part of Manufacturer without its prior consent, which consent shall not be unreasonably withheld.

- 14.3 Patient Release of Liability Regarding Expected Safety and Efficacy. Patients and physicians participating in the Expanded Access program shall be required to acknowledge the investigational nature of the treatment provided. Patients will provide written acknowledgement that no claim of efficacy or safety is made by Sponsor or Manufacturer and that Sponsor and Manufacturer are released from liability relating to any such perceived claims.

15 Insurance

- 15.1 Manufacturer shall maintain commercially reasonable insurance with coverage appropriate for its respective obligations hereunder with limits of at least \$3,000,000 per occurrence and \$5,000,000 in the aggregate.
- 15.2 The Sponsor shall maintain for the duration of the Study and thereafter for such period as is commercially reasonable clinical trial liability insurance, with limits of at least \$3,000,000 per occurrence and \$5,000,000 in the aggregate. Sponsor's clinical trials insurance shall include Manufacturer as additional insured.

16 Independent Contractor Relationship

The Parties are independent contractors. Nothing in this Agreement shall be construed to create the relationship of partners, joint ventures, or employer and employee between the Parties. Neither party, nor its employees, or independent contractors will have authority to act on behalf of or bind the other party in any manner whatsoever unless otherwise authorized in this Agreement or in a separate amendment signed by both Parties.

17 Term & Termination

- 17.1 The Term of this Agreement shall commence on the Effective Date of this Agreement and shall continue until the New Drug Application (NDA) for the study population is granted.
- 17.2 Notwithstanding the provision of Section 17.1 above, either Party may terminate this Agreement early in the event of any of the following:
- 17.2.1 Mutual consent
 - 17.2.2 Safety or compliance issues expressed via:
 - 17.2.2.1 Regulatory hold
 - 17.2.2.2 Internal determination of safety-related cause for termination or suspension of the EAP

- 17.2.3 Supply interruption, resulting in either:
 - 17.2.3.1 Order fulfillment delay of 3 months or greater, after enrollment has begun, or
 - 17.2.3.2 A known supply holdup of 6 months or greater.
- 17.2.4 Termination for material breach of IPSUA. Either Party may terminate this Agreement by written notice at a date set in the notice (allowing at least thirty (30) days for cure) in the event of a material breach of this Agreement by the other Party; provided that the breaching Party fails to cure such breach within thirty (30) days from the date of such notice.
- 17.2.5 Termination for material breach of Data License. Either Party may terminate this Agreement by written notice at a date sent in the notice (allowing at least thirty (30) days for cure) in the event of a material breach of **Agreement for Delivery and Licensed Use of Data Generated from OT-101 U.S. Expanded Access** ("Data License 1") by the other Party; provided that the breaching Party fails to cure such breach within thirty (30) days from the date of such notice.
- 17.2.6 Insolvency. If either Party shall become insolvent or shall make or seek to make an arrangement with, or an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy shall be instituted by, on behalf of or against such Party, or if a receiver or trustee of such Party's assets shall be appointed, or bankruptcy proceedings begin, the other Party may terminate this Agreement, as may be permitted by the applicable laws, with immediate effect.
- 17.3 Obligations after Termination and Wind-Down Activities. Upon notification of termination, the Parties agree to cooperate with each other to ensure an orderly wind-down of the Services and discharge of their respective obligations under this Agreement and applicable Law ("Wind-Down Activities"):
- 17.4 Subject to Applicable Law, upon the termination of the Agreement as provided above, the Sponsor will discontinue its use of the Investigational Product and will, upon direction from Manufacturer, return or destroy any remaining Investigational Product.
- 17.5 Survival. Sections 7, 10, 11, 13, 14, 15, 16, 17, 19, and 20 shall survive the termination of this Agreement howsoever caused.

18 Notices

Any notice or other communication required or permitted under this Agreement will be in writing and will be deemed given as of the date it is: (a) delivered by hand; (b) by electronic mail within on business day after such notice has been sent or (b) received, after it was sent, shipping prepaid, return receipt requested, by national courier service, to the party at the address listed below or subsequently specified in writing:

As to Sponsor:
WideTrial Inc.
8 The Green, Suite 8298
Dover, DE. 19901
Attn: Jess Rabourn
Telephone: (415) 637-4774
Email: jess.rabourn@widetrial.com

As to Manufacturer:
Oncotelic Inc.
29397 Agoura Road, Ste 107
Agoura Hills, CA 91301
Attn: Vuong Trieu
Telephone: (818-575-9560
Email: vtrieu@oncotelic.com

19 **Force Majeure**

- 19.1 No Party shall be considered to be in breach of this Agreement if it is prevented from fulfilling its obligations under this Agreement by Force Majeure, if instructed by regulatory or by law, or as a matter of safety.
- 19.2 Each Party will notify the other Party of any Force Majeure without undue delay.

20 **Governing Law and Venue**

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, U.S.A without regard for conflict of laws principles. The Parties consent to the exclusive jurisdiction and venue of the competent courts in Delaware, U.S.A.

21 **Miscellaneous**

- 21.1 Assignment. Neither party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other party. Any attempt to assign without compliance with this provision shall be void.
- 21.2 Entire Agreement. This Agreement, with all forthcoming Exhibits, in conjunction with the two Data License Agreements constitute the entire Agreement and understanding between the parties. It supersedes all prior discussions (whether oral or written) between the parties with regards to the subject matter, and neither party will be bound by conditions, definitions, warranties, understandings, or representations concerning such subject matter except as provided in this Agreement. This Agreement can only be modified by written Agreement duly signed by persons authorized to sign Agreements on behalf of both Manufacturer and Sponsor. In the event of any inconsistency between the terms of this Agreement and any attached Exhibits, the terms of this Agreement will prevail.
- 21.3 Waiver. The failure of a party in any instance to insist upon the strict performance of the terms of this Agreement will not be construed to be a waiver or relinquishment of any of the terms of this Agreement, either at the time of the party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect. All waivers of the terms of this Agreement shall be in writing.
- 21.4 Severability. Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this Agreement will not be affected thereby.
- 21.5 Titles. All titles and articles headings contained in this Agreement are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this Agreement or the intent of any of its provisions.

The undersigned have executed this Agreement as of the day and year noted below.

Oncotelic Inc.

WideTrial Inc.

Signature: /s/Vuong Trieu

Signature: /s/Jess Rabourn

Name: Vuong Trieu

Name: Jess Rabourn

Title: CEO

Title: CEO

Date: 9/5/2019

Date: 9/5/2019

**Agreement for Delivery and Licensed Use of Data Generated from OT-101 U.S. Expanded Access
(Data License 1 Agreement)**

between WideTrial and Oncotelic

This Agreement is made and entered into on September 5, 2019 (the "Effective Date"), by and between WideTrial Inc., a corporation headquartered at 8 The Green, Suite 8298, Dover, DE 19901 ("WideTrial") (the "Licensor"), and Oncotelic Inc., headquartered at 29397 Agoura Rd. Ste 107, Agoura Hills, CA 91301 ("Oncotelic") (the "Licensee") (each a "Party", collectively "Parties" to this bilateral Agreement).

WHEREAS, Licensor and Licensee intend to collaborate as Sponsor and Manufacturer, respectively, in a U.S. Expanded Access Program for treatment use of OT-101 for 25 or more patients in pancreatic cancer and other cancers known to overexpress TGF-B2 ("USEAPOT101", "The Expanded Access Program", "The EAP"), as defined and agreed to under the Parties' Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access ("IPSUA"), and

WHEREAS, Licensor endeavors to capture information and clinical data relating to patients treated in the Expanded Access Program ("USEAPOT101 Dataset" plus Safety Addendums, collectively for this Agreement known as the "Data") and to format and store the Data in Licensor's proprietary database, and

WHEREAS, Licensee desires to receive access to the Data from Licensor and receive license to use the Data in support of its commercial activities, subject to the terms and conditions of this Agreement, and

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

1. Definitions

- 1.1 "**Applicable Law**" means all laws, statutes, ordinances, codes, rules, and regulations that have been enacted by a Regulatory Authority in any jurisdiction relevant to the collection and management of clinical trial data and which are in force as of the Effective Date or come into force during the Term, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement, including, with respect to the United States, the Prescription Drug Marketing Act, the Federal Food, Drug and Cosmetics Act of 1938, as amended, The Federal Policy for the Protection of Human Subjects ("Common Rule"), and the Health Insurance Portability and Accountability Act ("HIPAA").
- 1.2 "**Course of Treatment**" means patients treatment with OT-101 consisting of 1-8 cycles, as described in the Protocol.
- 1.3 "**Data Tier**" means the level of granularity in which the referenced Dataset is to be transferred or disclosed, as defined in Sections 1.3 – 1.7 and summarized in **Exhibit 1**

- 1.4 **“Data Tier 1”** shall be defined as Discrete Observation-Level Data, which includes all information captured from the Expanded Access Program, including Protected Health Information (PHI) and treatment outcomes of individual patients.
- 1.5 **“Data Tier 2”** shall be defined as Patient-Level Aggregated Statistics, which are clinical statistics calculated and disclosed at the line-item level of each participating patient, including rates of progression, tumor size change, change of lab-calculated measures, number and frequency of AEs, and baseline and ending clinical scores.
- 1.6 **“Data Tier 3”** shall be defined as Trial-Specific Aggregate Statistics, calculated from data sets for which more than 50% of human subjects are from USEAPOT101 or more than 50% of total raw data volume is generated from USEAPOT101.
- 1.7 **“Data Tier 4”** shall be defined as Pooled Aggregate Statistics, which are calculated solely from data sets for which no more than 50% of human subjects are represented by USEAPOT101 and no more than 50% of total raw data volume is generated from USEAPOT101.
- 1.8 **“Data Tier 5”** shall be defined as Meta Data to include measures such as number of patients enrolled, number of sites, ranges of health conditions presented, and overall enrollment rate.
- 1.9 **“Expanded Access Program”** or **“EAP”** generally means an FDA-authorized clinical trial for the treatment use of an Investigational Product in patients who are not candidates to participate in any research trial for the particular Investigational Product. For purposes of this Agreement, **“The Expanded Access Program”** or **“The EAP”** means the particular Expanded Access Program contemplated by this Agreement for the treatment use of OT-101 in patients with pancreatic cancer and other cancers characterized by overexpression of TGF-B2.
- 1.10 **“Health Insurance Portability and Accountability Act of 1996”** or **“HIPAA”** is the U.S. regulation of healthcare-related data privacy described in the Code of Federal Regulations Title 45, Parts 160 and 164.
- 1.11 **“Investigational New Drug Filing”**, or **“IND”** is a required written claim of exemption from the Food, Drug, and Cosmetic Act prohibition on interstate delivery of investigational therapeutics for pre-market use in humans, for authorized research programs or treatment-use programs. For this Agreement, **“The IND”** or **“The INDs”** shall refer to the specific filing(s) submitted by the Sponsor to FDA for 30-day authorization of The Expanded Access Program.
- 1.12 **“IND Authorization”** means the passage of 30 days after submission of properly assembled EAP IND to the appropriate FDA review division with no response from FDA review division, OR an affirmative statement of authorization from the FDA review division.

- 1.13 **“Personally Identifiable Information”** or **“PII”** means data that directly or indirectly could be used to identify individuals in association with sensitive personal information. E.g. Name, social security number, address, medical record number.
- 1.14 **“Protected Health Information”** or **“PHI”** is individually identifiable health information created by health care providers, as defined in the HIPAA Privacy Rule.
- 1.15 **“Privacy Rule”** is the set of requirements under HIPAA defining the permitted capture and electronic transfer of Protected Health Information in clinical programs including Expanded Access Programs, codified in *45CFR160* and *45CFR164 Subparts A and E*.
- 1.16 **“Protocol”** is the clinical plan for Expanded Access, including eligibility criteria, treatment regimen, and data capture, included in The IND(s) for the particular study population and authorized by FDA and IRB(s).
- 1.17 **“Publication Date”** is the earlier of (a) the date of Licensee’s first publication of clinical results of the EAP or (b) 12 months following the completion of the program.
- 1.18 **“Release Date”** is 12 months after the first market approval for OT-101.

2 License.

- 2.1 License Grant. Subject to Licensee’s compliance with all other terms of this Agreement and conditioned on Licensee’s payment of Fees, Licensor hereby grants Licensee a perpetual, transferable license to the full USEAPOT101 Dataset with partial exclusivity as defined in Section 2.2
- 2.2 Exclusivity. Licensee’s right to disclose or transfer The Data shall be exclusive to Licensee for periods of time according to the levels of data disclosure or transfer contemplated, as defined below:
 - 2.2.1 Data Tier 1: the right to disclose or transfer Discrete Observation-Level Data shall remain exclusively with the Licensee until the Release Date, as defined in Section 1.18. This right of Licensee to transfer Tier 1 Data to third parties is subject to and may be limited by HIPAA Privacy Rule.
 - 2.2.2 Data Tier 2: the right to disclose or transfer Patient-Level Aggregate Statistics shall remain exclusively with the Licensee until the Release Date, as defined in Section 1.18.

- 2.2.3 Data Tier 3: the right to disclose or transfer Trial-Specific Aggregated Statistics, including inventions or derivations based primarily on the Data, shall remain exclusively with the Licensee until the Release Date, as defined in Section 1.18.
- 2.2.4 Data Tier 3: Notwithstanding the exclusivity provided generally in 2.2.3, certain Trial-Specific Aggregated Statistics that are publicly released by the Licensee may subsequently be released by the Licensor upon the Publication Date, as defined in section 1.17.
- 2.3 Licensor Regulatory Compliance. Notwithstanding the above exclusivity of Licensee's data transfer rights for commercial purposes, Licensor reserves the right to disclose any part of the USEAPOT101 Dataset to participating Investigators, IRBs, FDA, or any other authority as needed for safety reporting and any other purpose required by Applicable Law.
- 2.4 Reservation of Rights. Licensor reserves all rights not expressly granted to Licensee in this Agreement.

3 Delivery and Content of Data

- 3.1 Delivery. Licensee shall have full view and full download access to the USEAPOT101 Dataset within Licensor's clinical trial management system, beginning with first patient enrolled.
- 3.2 Content. USEAPOT101 Dataset shall include the following, as defined by the Protocol:
 - 3.2.1 Meta Data relating to overall enrollment and conduct of the program
 - 3.2.2 Clinical Trial Data including patient screening information, concomitant medications, co-morbidities, baseline clinical assessment, interim and ending clinical assessment, adverse event log, and -as available- imagery and lab tests captured throughout treatment period under patient's standard of care
 - 3.2.3 Patient-specific identification code mapped to key held by health care provider
- 3.3 Safety Addendums. All event-specific safety information shall be made available to Licensee for the purpose of enabling Licensee's compliance with regulatory reporting requirements. These addendums shall comprise safety event processing forms and relevant correspondence, SAE narratives, SUSAR reports, regulatory correspondence with IRB(s) and FDA, and transcripts of MedWatch filings. These addendums shall be considered separate from the USEAPOT101 Dataset.

3.4 Compliance with Privacy Rule. Licensee warrants that it understands HIPAA definition for Protected Health Information (PHI) and that permissible transfer of PHI to other parties for research purposes is legally permissible only under certain conditions as defined in Section 4 of this Agreement and subject to *Code of Federal Regulations Title 45 Sections 160 and 164*.

3.5 Covenant to Secure Data. Licensee covenants to maintain all parts of the USEAPOT101 Dataset in a secure manner.

4 HIPAA Compliance and Data Use Agreement under Privacy Rule

4.1 PHI in Data Tier 1. The USEAPOT101 Dataset shall not include personally identifiable information (PII). But it shall include specific dates of treatment and safety events, and therefore Tier 1 may not qualify as *de-identified data* under the HIPAA Privacy Rule and therefore must be treated as Protected Health Information (PHI).

4.2 Permissible Use of PHI that excludes PII. Use and disclosure of Protected Health Information (PHI) is permissible without written authorization from the patient, provided there is no Personally Identifiable Information (PII) in the dataset and provided the resulting “Limited Data Set” is transferred under a “Data Use Agreement” as composed in Section 4.3.

4.3 Data Use Agreement. As required by HIPAA Privacy Rule, Licensee hereby agrees to the following covenants of data privacy:

4.3.1 Licensee is not permitted to use or further disclose the Limited Data Set in a way that, if done by the Health Care Provider, would violate the Privacy Rule.

4.3.2 Licensee will use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the Agreement, and report to the Licensor any uses or disclosures in violation of the Agreement of which the Licensee becomes aware.

4.3.3 Licensee will hold any agent or subcontractor to the standards, restrictions, and conditions stated in this Data Use Agreement with respect to the information.

4.3.4 Licensee will not use the Data to support attempts to identify or contact any of the patients involved in the EAP.

4.4 Use of Safety Addendum Information. The Licensee may also receive safety event documentation, defined in 3.3, that reveals Personally Identifiable Information (PII) and therefore constitutes Protected Health Information (PHI). Licensor agrees to not use or disclose this information for research purposes without (a) redacting all PII and (b) implementing a Data Use Agreement with any subsequent recipient of the information.

- 4.5 Other Uses or Disclosures. Under Safe Harbor provision of the Privacy Rule, Data Tier 2 is considered *de-identified data* because it does not include PII and does not include specific dates of treatment or safety events. Data Tiers 2-5 do not meet the definition of PHI and therefore are not restricted by HIPAA Privacy Rule in their use or disclosure.
- 4.6 Liability. The Licensor shall not be responsible for any Privacy Rule violations made by the Licensee in its use or disclosure of USEAPOT101 Dataset or related Safety Addendums.

5 Intellectual Property Ownership.

- 5.1 Licensee acknowledges that, as between Licensee and Licensor, Licensor owns all right, title, and interest in and to the Data. Licensee further acknowledges that: (a) the Data is an original compilation protected by United States copyright laws and (b) Licensor has dedicated substantial resources to collect, manage, and compile the Data. Licensee agrees that it will be considered a material breach by Licensee under this Agreement if Licensee contests any of Licensor's right, title, or interest in or to the Data, including without limitation, in a judicial proceeding anywhere throughout the world.
- 5.2 Notwithstanding Licensor's Data ownership, as defined in 5.1 of this Agreement, any derivation of the Data created by the Licensee, including analyses, discoveries, and inventions shall be regarded as the intellectual property of the Licensee.

6 Fees and Payment

- 6.1 Data Fee. In consideration for delivery and license of the USEAPOT101 Dataset and Safety Addendums, Licensee shall pay Licensor USD 2500 per patient treated, for up to 150 patients. After 150 patients have been registered, the Data Fee shall be USD 1500 per patient.
- 6.2 Count of Patients. For its use in this section of the Agreement, a "Patient" shall mean a patient's single Course of Treatment, which comprises 1-8 individual cycles. If the same patient returns for a second Course of Treatment, 6 or more months after completing the first Course of Treatment, he or she shall be considered a new additional patient and shall be counted a second time.
- 6.3 Timing of Payments.
- 6.3.1 First Payment. Upon FDA IND Authorization of the first IND submitted for UAEAPOT101, Licensee shall complete its payment to the Licensor for the first 12 patients, equaling a fixed sum of USD 30,000.
- 6.3.2 Second Payment. Upon start of treatment of the 6th patient, Licensee shall complete its payment to the Licensor for the 13th through 25th patients, equaling a fixed sum of USD 32,500.

6.3.3 Subsequent Payment. If the number of patients exceeds 25, Data Fee shall be paid for each additional patient within 30 days of start of treatment.

6.4 Investigator Allowance. On behalf of Licensee, Licensor may pay certain health care providers (HCPs) up to \$1500 per treated patient to cover clinical coordination and data entry costs at the particular site. These costs will be passed through to Licensee on the same billing cycle under which the Licensor agrees to pay the HCP. Licensee hereby agrees to reimburse Licensor for these payments within the billing cycle presented.

7 **Disclaimer of Warranties**. The Data is provided “As Is” and Licensor hereby disclaims all warranties, whether express, implied, statutory, or otherwise. Licensor specifically disclaims all implied warranties of merchantability, fitness for a particular purpose, title, and non-infringement, and all warranties arising from course of dealing, usage or trade practice, licensor makes no warranty of any kind that the data, or any products or results of its use, will meet licensee’s or any other person’s requirements, operate without interruption, achieve any intended result, be compatible or work with any software, system, or other services, or be free of harmful code or errors.

8 **Exclusion of Liability**. Subject to the indemnification obligations set forth in Section 9, in no event shall either Party be liable (including without limitation, contract, and tort liability) for any indirect, incidental, punitive, exemplary, special or consequential damages, loss of profit, or costs of substitute services suffered by the other Party or any third party, however caused, regardless of the theory of liability, whether in contract, tort, product liability or otherwise

9 **Indemnification**

9.1 Licensee Indemnification: Licensee shall hold harmless, indemnify, and defend Licensor from and against any claim, liability, loss, damage or expense, including, without limitation, reasonable attorneys’ fees (collectively, “Loss”), arising out of any third party claim resulting from the use of the misuse of the Data, provided that Licensee’s obligation to hold harmless, indemnify and defend as aforesaid shall be proportionately reduced and shall not apply to the extent that such Loss is the result of Licensor’s act of fraud, negligence or willful misconduct or breach of Applicable Law, and further provided that Licensee is notified in writing as soon as practicable under the circumstances of any complaint or claim potentially subject to indemnification and has full control of any disposition or settlement of such claim, and Licensor and everyone on its behalf has fully cooperated with Licensee regarding such disposition or settlement; provided however that Licensee shall not dispose or settle any claim admitting liability on the part of Licensor without its prior consent, which consent shall not be unreasonably withheld.

9.2 Licensor Indemnification. The Licensor shall hold harmless, indemnify, and defend Licensee for any Loss arising out of: (i) Licensor's own or any of its representatives' or agents' act of fraud, negligence or willful misconduct (ii) breach of this Agreement (iii) failure to manage the data according to HIPAA Privacy Rule; (iv) breach of Applicable Law or regulation, provided that Licensor's obligation to hold harmless, indemnify and defend as aforesaid shall be proportionately reduced and shall not apply to the extent that such Loss is the result of Licensee's act of fraud, negligence or willful misconduct or breach of Applicable Law, and further provided that the Licensor is notified in writing as soon as practicable under the circumstances of any complaint or claim and has full control of any disposition or settlement of such claim, and Licensee and everyone on its behalf has fully cooperated with the Licensor regarding such disposition or settlement; provided however that the Licensor shall not dispose or settle any claim admitting liability on the part of Licensee without its prior consent, which consent shall not be unreasonably withheld.

10 Term & Termination

10.1 Term. The Term of this Agreement shall commence on the Effective Date of this Agreement and shall continue through the completion of The Expanded Access Program as defined in Section 16.1 of the "**Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access (IPSUA)**"

10.2 Privacy Breach by Licensee. Notwithstanding provision of Section 10.1, Licensor may terminate this Agreement, with possible revocation of License -if required by law- in the event of Licensee's material breach of the data privacy provisions herein, including Sections 3.4, 4.3, and 4.4.

10.3 Early Termination of EAP. Notwithstanding provision of Section 10.1, Licensor may terminate this Agreement, without refund of any paid data fees as described in Sections 6.3.1 and 6.3.2, in the event of any of the following:

10.3.1 Non-Sponsor-caused early termination of The Expanded Access Program due to causes cited in Section 16.2 of the **IPSUA**

10.3.2 In the capacity of Manufacturer, Licensee's material breach of the IPSUA

10.3.3 Licensee's material breach of this Agreement

10.3.4 Licensee's material breach of Data License 2 Agreement

10.4 Material Breach by Licensor. Notwithstanding the provision of Section 10.1, the Licensee may terminate this Agreement in the event of any of the following:

10.4.1 Licensor's material breach of this Agreement

10.4.2 Licensor's material breach of Data License 2 Agreement

10.4.3 In the capacity of Sponsor, Licensor's material breach of the IPSUA

- 10.5 Survival of License. With the exception of any legally required revocation of License, as described in Section 10.2, termination of this Agreement shall not invalidate the perpetual License to full use of the data that has already been delivered as described Sections 2 and 3.
- 10.6 The Parties may terminate this Agreement by Mutual Consent.
- 10.7 Obligations after Termination and Wind-Down Activities. Upon notification of termination, the Parties agree to cooperate with each other to ensure an orderly wind-down of the Services and discharge of their respective obligations under this Agreement and applicable Law (“Wind-Down Activities”):
- 10.7.1 Subject to Applicable Law, upon the termination of the Agreement as provided above, the Sponsor will discontinue its use of the Investigational Product and will, upon direction from Manufacturer, return or destroy any remaining Investigational Product.
- 10.8 Survival. Sections 1, 2, 4, 5, 7, 8, 9, 12, and 13 shall survive the termination of this Agreement howsoever caused.

11 Force Majeure

- 11.1 No Party shall be considered to be in breach of this Agreement if it is prevented from fulfilling its obligations under this Agreement by Force Majeure, if instructed by regulatory or by law, or as a matter of safety.
- 11.2 Each Party will notify the other Party of any Force Majeure without undue delay.

12 Governing Law and Venue

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, U.S.A without regard for conflict of laws principles. The Parties consent to the exclusive jurisdiction and venue of the competent courts in Delaware, U.S.A.

13 Miscellaneous

- 13.1 Assignment. Neither party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other party. Any attempt to assign without compliance with this provision shall be void.
- 13.2 Entire Agreement. This Agreement, with all forthcoming Exhibits, in conjunction with the IPSUA and Data License 2, constitute the entire scope of Agreement and understanding between the parties. It supersedes all prior discussions (whether oral or written) between the parties with regards to the subject matter, and neither party will be bound by conditions, definitions, warranties, understandings, or representations concerning such subject matter except as provided in this Agreement. This Agreement can only be modified by written Agreement duly signed by persons authorized to sign Agreements on behalf of both Manufacturer and Sponsor. In the event of any inconsistency between the terms of this Agreement and any attached Exhibits, the terms of this Agreement will prevail.

- 13.3 Waiver. The failure of a party in any instance to insist upon the strict performance of the terms of this Agreement will not be construed to be a waiver or relinquishment of any of the terms of this Agreement, either at the time of the party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect. All waivers of the terms of this Agreement shall be in writing.
- 13.4 Severability. Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this Agreement will not be affected thereby.
- 13.5 Titles. All titles and articles headings contained in this Agreement are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this Agreement or the intent of any of its provisions.

The undersigned have executed this Agreement as of the day and year noted below.

Oncotelic Inc.

WideTrial Inc.

Signature: /s/ Vuong Trieu

Signature: /s/ Jess Rabourn

Name: Vuong Trieu

Name: Jess Rabourn

Title: CEO

Title: CEO

Date: 9/5/2019

Date: 9/5/2019

EXHIBIT 1

SUMMARY OF USEAPOT101 DATA TIERS

Data Tier	Data Tier Name	Data Tier Description	WT right of disclosure	HIPAA Privacy Compliance
5	Meta Data	Number of patients, range of conditions included, sites, enrollment rates, etc.	WT retains transfer and publication rights.	No PHI disclosed
4	Pooled Aggregate Statistics	Statistics calculated from data sets comprising not more than 50% of human participants from OT101EAP and not more than 50% of total raw data volume generated from OT101EAP	WT retains transferability and publication rights.	No PHI disclosed
3	Trial-Specific Aggregate Statistics	Statistics calculated solely from data sets comprising more than 50% of human participants from OT101EAP and more than 50% of total raw data volume generated from OT101EAP	Manufacturer retains exclusive right to transfer and publish through First Publication Date, after which the right is shared with WT and participating Investigators. First Publication Date to be the earlier of Manufacturer's first publication of program results or 12 months after completion of program.	No PHI disclosed
2	Patient-Level Aggregate Statistics	Clinical statistics calculated and disclosed at the line-item level of each participating patient, including rates of progression, tumor size change, change of lab-calculated measures, number and frequency of AEs, and base line and ending clinical scores.	Manufacturer retains exclusive right to transfer and publish through Release Date, which is 12 months after first market approval for OT-101.	Likely qualifies as de-identified under Safe Harbor; otherwise more likely under "Expert Rule". Can be disclosed further if de-identified. "Limited Data Set"; no direct identifiers.
1	Discrete Observation-Level Data	Includes all data captured in program. Disclosed at observation-level.	Subject to WT's regulatory reporting requirements, Manufacturer retains exclusive right to transfer through Release Date, which is defined above. WT holds "Limited Data Set" with no direct identifiers.	Captured and delivered without personally identifiable information and thus qualifies as "Limited Data Set". Can be disclosed under "Data Use Agreement".

For purposes of defining transferability and disclosure rights, Tiers 2, 3, and 4 may -at Licensor's discretion- include supplemental data on the OT101EAP subjects, gathered by Licensor outside the protocol (e.g. E.H.R. data, additional follow-up submitted as survey data or ePRO)

**Agreement for Delivery and Licensed Use of WideTrial Bonus Dataset
(Data License 2 Agreement)**

between WideTrial and Oncotelic

This Agreement is made and entered into on September 5, 2019 (the "Effective Date"), by and between WideTrial Inc., a corporation headquartered at 8 The Green, Suite 8298, Dover, DE 19901 ("WideTrial") (the "Licensor"), and Oncotelic Inc., headquartered at 29397 Agoura Rd. Ste 107, Agoura Hills, CA 91301 ("Oncotelic") (the "Licensee") (each a "Party", collectively "Parties" to this bilateral Agreement).

WHEREAS, Licensor and Licensee intend to collaborate as Sponsor and Manufacturer, respectively, in a U.S. Expanded Access Program for treatment use of OT-101 in 25 or more cancer patients ("USEAPOT101"), as defined and agreed to under the Parties' Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access ("IPSUA"), and

WHEREAS, Licensor, in its ongoing activities, expects to generate clinical data from multiple sponsored Expanded Access programs in the future and will retain control over this data, subject to various specific agreements and Release Dates as negotiated between Licensor and the particular manufacturers, and

WHEREAS, Licensor intends to maintain a Bonus Dataset that comprises all captured clinical data from its sponsored Expanded Access Programs and is available for Licensor's commercial use, including transfer, and

WHEREAS, Licensee desires to have access and license to Bonus Dataset from Licensor, subject to the terms and conditions of this Agreement, and

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

1. Definitions

1.1 **"Applicable Law"** means all laws, statutes, ordinances, codes, rules, and regulations that have been enacted by a Regulatory Authority in any jurisdiction relevant to the collection and management of clinical trial data and which are in force as of the Effective Date or come into force during the Term, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement, including the Prescription Drug Marketing Act, the Federal Food, Drug and Cosmetics Act of 1938, as amended, The Federal Policy for the Protection of Human Subjects ("Common Rule"), the Health Insurance Portability and Accountability Act ("HIPAA").

1.2 **"Data License 1 Agreement"** is the **Agreement for Delivery and Licensed Use of Data Generated from OT-101 U.S. Expanded Access**

- 1.3 **“Expanded Access Program”** or **“EAP”** means an FDA-authorized clinical trial for the treatment use of an Investigational Product in patients who are not candidates to participate in any research trial for the particular Investigational Product.
- 1.4 **“EAP Dataset”** shall mean the dataset generated from any particular Expanded Access Program sponsored by WideTrial and whose availability and transferability is determined through negotiated agreement and release dates with the particular manufacturer.
- 1.5 **“Health Insurance Portability and Accountability Act of 1996”** or **“HIPAA”** is the U.S. regulation of healthcare-related data privacy described in the Code of Federal Regulations Title 45, Parts 160 and 164.
- 1.6 **“Investigational New Drug Filing”**, or **“IND”** is a required written claim of exemption from the Food, Drug, and Cosmetic Act prohibition on interstate delivery of investigational therapeutics for pre-market use in humans, for authorized research programs or treatment-use programs. For this Agreement, **“The IND”** or **“The INDs”** shall refer to the specific filing(s) submitted by the Sponsor to FDA for 30-day authorization of The Expanded Access Program.
- 1.7 **“IPSUA”** is the **Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access**, the definitive Agreement of terms and conditions for Licensee’s -in the capacity of Manufacturer- provision of Investigational Drug supply for USEAPOT101.
- 1.8 **“Personally Identifiable Information”** or **“PII”** means data that directly or indirectly could be used to identify individuals in association with sensitive personal information. e.g. Name, social security number, address, medical record number.
- 1.9 **“Protected Health Information”** or **“PHI”** is individually identifiable health information created by health care providers, as defined in the HIPAA Privacy Rule.
- 1.10 **“Privacy Rule”** is the set of requirements under HIPAA defining the permitted capture and electronic transfer of Protected Health Information in clinical programs including Expanded Access Programs, codified in *45CFR160* and *45CFR164 Subparts A and E*.
- 1.11 **“Protocol”** is the clinical plan for Expanded Access, including eligibility criteria, treatment regimen, and data capture, included in The IND(s) for the particular study population and authorized by FDA and IRB(s).

- 1.12 **“Publication Date”** is the earlier of (a) the date of Licensee’s first publication of clinical results of the EAP or (b) 12 months following the completion of the program.
- 1.13 **“Release Date”** is the date a particular EAP dataset becomes available for WideTrial’s commercial use and disclosure; it is also the date upon which the data from a particular EAP dataset shall be added to the Bonus Dataset.
- 1.14 **“The Bonus Dataset”** means the deliverable dataset contemplated by this Agreement, consisting of all clinical data that is available for release, subject to limitations described in Section 3.2.
- 1.15 **“USEAPOT101”** shall mean the U.S. Expanded Access Program contemplated in the Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access (IPSUA)”

2 **Intellectual Property Ownership.** Licensee acknowledges that, as between Licensee and Licensor, Licensor owns all right, title, and interest, including all intellectual property rights, in the Bonus Dataset. Licensee further acknowledges that: (a) the Bonus Dataset is an original compilation protected by United States copyright laws, (b) the Bonus Dataset is trade secret, and (c) Licensor has dedicated substantial resources to collect, manage, and compile the Bonus Dataset. Licensee agrees that it will be considered a material breach by Licensee under this Agreement if Licensee contests any of Licensor’s right, title, or interest in or to the Bonus Dataset, including without limitation, in a judicial proceeding anywhere throughout the world. Subject to the above and the Permitted Use as defined in Section 4.3 of this Agreement, Parties agree that derivative work products created by licensee through use of the Bonus Dataset, i.e. statistical analysis/ AI modeling tools, shall belong to Licensee.

3 **Delivery and Content of Data**

- 3.1 **Delivery.** Licensee shall be provided a password-permissioned link which allows download of a prepared export file of the most up-to-date version of the Bonus Dataset, subject to limitations described in Section 3.2. Export file will be updated, with notification sent to Licensee within 30 days of every Release Date of additional data in the Bonus Dataset.
- 3.2 **Scope of Bonus Dataset.** Bonus Dataset shall consist of all captured, legally transferable clinical trial data from WideTrial-sponsored EAPs until the Dataset includes data from at least 1000 total patients, of which at least 500 are in EAPs for cancer treatment.

3.3 Content. Bonus Dataset shall include the following:

- 3.3.1 All captured clinical trial data to include, as available from each EAP and as permissibly transferred under Applicable Law and EAP-specific data licenses, including baseline clinical assessment and score, interim and ending clinical assessment and score, adverse event log, and -as available- imagery, biomarkers, and lab tests captured throughout treatment period under patient's standard of care and according to the particular EAP protocol.
- 3.3.2 Relative time intervals (or actual calendar dates) for baseline date, treatment date and recorded event dates, as available under Privacy Rule and program-specific Data Use Agreements
- 3.3.3 Patient-specific unique identification code mapped to each patient-level line item.

3.4 Limitations

- 3.4.1 No PII. Safety event processing forms -including medical narratives – which are considered “Safety Addendums” in Data License 1 may be excluded from the Bonus Dataset due to the non-transferability of Personally Identifiable health Information (PII) without study-specific patient authorization.
- 3.4.2 Limited PHI. The transferability of Protected Health Information (PHI) will be subject to determinations of *de-identification* and EAP-specific Data Use Agreements, as required under HIPAA Privacy Rule and IRB authorizations, and therefore may impact the volume and timing of data provided at the Tier 1 level of data granularity.

3.5 Compliance with Privacy Rule. Licensee warrants that it understands HIPAA definition for Protected Health Information (PHI) and that receipt of datasets that may include PHI requires, at minimum, a “Data Use Agreement” as composed in Section 3.4.1.

- 3.5.1 Data Use Agreement. As required by 45 CFR 164, Licensee hereby agrees to the following covenants of data privacy regarding the Bonus Dataset:
 - 3.5.1.1 Licensee is not permitted to use or further disclose the Limited Data Set in a way that, if done by the Health Care Provider, would violate the Privacy Rule.
 - 3.5.1.2 Licensee will use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the Agreement, and report to the Licensor any uses or disclosures in violation of the Agreement of which the Licensee becomes aware.
 - 3.5.1.3 Licensee will hold any agent or subcontractor to the standards, restrictions, and conditions stated in this Data Use Agreement with respect to the information.
 - 3.5.1.4 Licensee will not use the Dataset for attempts to identify or contact any of the patients involved in the EAP.

4 **License**

- 4.1 **License Grant.** Subject to the conditions set forth in Section 4.2 of this Agreement and Licensee's compliance with all other terms of this Agreement, Licensor hereby grants Licensee a perpetual, non-transferable, non-exclusive license to use the Bonus Dataset for Licensee's Permitted Use as defined in Section 4.3 of this Agreement.
- 4.2 **Conditions.** The License is subject to the following conditions:
- 4.2.1 Data License 1 has not been terminated due to Licensee's non-payment of fees, and
- 4.2.2 Licensee, in its capacity as Manufacturer for USEAPOT101, has neither stopped nor suspended supply, nor -for any other reason- unilaterally terminated USEAPOT101 prior to the enrollment of 25 patients, and
- 4.2.3 USEAPOT101 has not been terminated due to safety-related issues prior to enrollment of 25 patients.
- 4.3 **Permitted Use.** The Permitted Use of the Bonus Dataset is the internal research, development, and training of Licensee's quantitative analysis systems which may include -without limitation- disease models, covariate analysis, and biomarker discovery and may serve to inform internal decision making. Permitted Use does **not include** further disclosure of any portion of the Bonus Dataset at any level of granularity. Intellectual property obtained from Permitted Use shall belong to Licensee.
- 4.4 **Restricted Use.** Licensee shall only use the Bonus Dataset for the Permitted Use and shall not disclose, release, distribute, or deliver the Bonus Dataset, or any portion thereof, or any derivation thereof to any third party without Licensor's prior written consent. Any purpose or use not specifically authorized herein is prohibited unless otherwise agreed to in writing by Licensor. Without limiting the foregoing and except as otherwise expressly set forth in this Agreement, Licensee shall not at any time, directly or indirectly: (i) rent, lease, lend, sell, sublicense, assign, distribute, publish, transfer, or otherwise make available the Bonus Dataset; (iii) publish, enhance, or display any compilation or directory based upon information derived from the Bonus Dataset; or (vi) use the Bonus Dataset in any manner or for any purpose that infringes, misappropriates, or otherwise violates any intellectual property right or other right of any person, or that violates any applicable law.
- 4.5 **Reservation of Rights.** Licensor reserves all rights not expressly granted to Licensee in this Agreement.

5 **Disclaimer of Warranties.** The Bonus Dataset is provided “As Is” and Licensor hereby disclaims all warranties, whether express, implied, statutory, or otherwise. Licensor specifically disclaims all implied warranties of merchantability, fitness for a particular purpose, title, and non-infringement, and all warranties arising from course of dealing, usage or trade practice, Licensor makes no warranty of any kind that the Bonus Dataset, or any products or results of its use, will meet Licensee’s or any other person’s requirements, operate without interruption, achieve any intended result, be compatible or work with any software, system, or other services, or be free of harmful code or errors.

6 **Exclusion of Liability.** Subject to the indemnification obligations set forth in Section 7, in no event shall either Party be liable (including without limitation, contract, and tort liability) for any indirect, incidental, punitive, exemplary, special or consequential damages, loss of profit, or costs of substitute services suffered by the other Party or any third party, however caused, regardless of the theory of liability, whether in contract, tort, product liability or otherwise.

7 **Indemnification**

7.1 **Licensee Indemnification:** Licensee shall hold harmless, indemnify, and defend Licensor from and against any claim, liability, loss, damage or expense, including, without limitation, reasonable attorneys’ fees (collectively, “Loss”), arising out of any third party claim resulting from the use of the misuse of Bonus Dataset provided that Licensee’s obligation to hold harmless, indemnify and defend as aforesaid shall be proportionately reduced and shall not apply to the extent that such Loss is the result of Licensor’s act of fraud, negligence or willful misconduct or breach of Applicable Law, and further provided that Licensee is notified in writing as soon as practicable under the circumstances of any complaint or claim potentially subject to indemnification and has full control of any disposition or settlement of such claim, and Licensor and everyone on its behalf has fully cooperated with Licensee regarding such disposition or settlement; provided however that Licensee shall not dispose or settle any claim admitting liability on the part of Licensor without its prior consent, which consent shall not be unreasonably withheld.

7.2 **Licensor Indemnification.** The Licensor shall hold harmless, indemnify, and defend Licensee for any Loss arising out of: (i) Licensor’s own or any of its representatives’ or agents’ act of fraud, negligence or willful misconduct (ii) breach of this Agreement (iii) failure to manage the data according to HIPAA Privacy Rule; (iv) breach of Applicable Law or regulation, provided that Licensor’s obligation to hold harmless, indemnify and defend as aforesaid shall be proportionately reduced and shall not apply to the extent that such Loss is the result of Licensee’s act of fraud, negligence or willful misconduct or breach of Applicable Law, and further provided that the Licensor is notified in writing as soon as practicable under the circumstances of any complaint or claim and has full control of any disposition or settlement of such claim, and Licensee and everyone on its behalf has fully cooperated with the Licensor regarding such disposition or settlement; provided however that the Licensor shall not dispose or settle any claim admitting liability on the part of Licensee without its prior consent, which consent shall not be unreasonably withheld.

8 **Term & Termination**

- 8.1 The Term of this Agreement shall commence on the Effective Date of this Agreement.
- 8.2 The Licensor may terminate this Agreement, with revocation of License, in the event of either of the following:
 - 8.2.1 Licensee’s material breach of Data License 1 Agreement
 - 8.2.2 Licensee’s material breach of this Agreement
- 8.3 The Parties may terminate this Agreement by Mutual Consent.
- 8.4 Obligations after Termination and Wind-Down Activities. Upon notification of termination, the Parties agree to cooperate with each other to ensure an orderly wind-down of the Services and discharge of their respective obligations under this Agreement and applicable Law (“Wind-Down Activities”):
- 8.5 Survival. Sections 1, 2, 5, 6, 7, 8, 10, and 11 shall survive the termination of this Agreement howsoever caused.

9 **Force Majeure**

- 9.1 No Party shall be considered to be in breach of this Agreement if it is prevented from fulfilling its obligations under this Agreement by Force Majeure, if instructed by regulatory or by law, or as a matter of safety.
- 9.2 Each Party will notify the other Party of any Force Majeure without undue delay.

10 **Governing Law and Venue**

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, U.S.A without regard for conflict of laws principles. The Parties consent to the exclusive jurisdiction and venue of the competent courts in Delaware, U.S.A.

11 **Miscellaneous**

- 11.1 Assignment. Neither party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other party. Any attempt to assign without compliance with this provision shall be void.
- 11.2 Entire Agreement. This Agreement, with all forthcoming Exhibits, in conjunction with the IPSUA and Data License 1 Agreement, constitute the entire scope of Agreement and understanding between the parties. It supersedes all prior discussions (whether oral or written) between the parties with regards to the subject matter, and neither party will be bound by conditions, definitions, warranties, understandings, or representations concerning such subject matter except as provided in this Agreement. This Agreement can only be modified by written Agreement duly signed by persons authorized to sign Agreements on behalf of both Manufacturer and Sponsor. In the event of any inconsistency between the terms of this Agreement and any attached Exhibits, the terms of this Agreement will prevail.

- 11.3 Waiver. The failure of a party in any instance to insist upon the strict performance of the terms of this Agreement will not be construed to be a waiver or relinquishment of any of the terms of this Agreement, either at the time of the party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect. All waivers of the terms of this Agreement shall be in writing.
- 11.4 Severability. Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this Agreement will not be affected thereby.
- 11.5 Titles. All titles and articles headings contained in this Agreement are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this Agreement or the intent of any of its provisions.

The undersigned have executed this Agreement as of the day and year noted below.

Oncotelic Inc.

WideTrial Inc.

Signature: /s/Vuong Trieu

Signature: /s/Jess Rabourn

Name: Vuong Trieu

Name: Jess Rabourn

Title: CEO

Title: CEO

Date: 9/5/2019

Date: 9/5/2019

Mateon Partners with WideTrial for Data-Generating Expanded Access Programs in Cancer

AGOURA HILLS, California and SAN FRANCISCO, California, September 9th, 2019 -- Mateon Therapeutics Inc. (OTCQB:MATN), announced today that it has executed agreements with WideTrial Inc. for an Expanded Access program (EAP) in pancreatic cancer. Using WideTrial's novel platform, the investigational therapeutic OT-101 will be made available for elective treatment-use to patients who do not meet the inclusion criteria of OT-101 research trials. The partnership may also support Expanded Access for OT-101 in additional patients with advanced solid tumors, excluding brain cancers (AA, GBM, and other gliomas). Separately, the companies executed data access agreements to support the development of Mateon's AI/Blockchain technologies with WideTrial's data assets in cancer and other therapeutic areas.

OT-101 is a first-in-class RNA therapeutic targeting TGF beta and is the lead immune-oncology drug candidate of Oncotelic, a wholly owned subsidiary of Mateon Therapeutics Inc.. The investigational drug exhibited single-agent activity in relapsed/refractory cancer patients during multiple Phase 2 clinical trials.

Like research trials, cohort Expanded Access programs (EAPs) are centrally monitored trials that enroll patients at designated sites under a single protocol. They differ from research trials in that their primary objective is to provide the option of treatment-use to patients who cannot take part in the product's research trials.

"This Expanded Access program will allow us to meet the spirit of clinical trial inclusivity, as described in the 2017 FDA Reauthorization Act. We are pleased to have found a viable way to accommodate greater numbers of patients in need and the doctors who seek to treat them," said Dr. Vuong Trieu, Chairman and CEO of Mateon Therapeutics Inc.. "Though the primary objective is treatment, we intend to utilize generated data to improve the power and targeting of future research trials."

"The PointR platform applies cutting edge algorithms to clinical datasets and could be used to quickly and cost-effectively identify the best therapy tailored fit to a single individual. The ability to access EAP data is helpful to the development of this platform" said Saran Saund, CEO of PointR Data, which is becoming a wholly owned subsidiary of Mateon Therapeutics Inc.. "We are thrilled at the opportunity of vertically integrating artificial intelligence and drug development capabilities under one roof to quickly identify promising new therapeutic opportunities for various diseases and to deliver compelling business value."

"We built WideTrial to solve the economic and operational barriers that drug developers face with Expanded Access," said Jess Rabourn, CEO of WideTrial. "The new platform enables larger numbers of gravely ill patients to choose to try investigational medicines under a properly designed protocol. Although treatment is the primary objective, EAP sponsors can learn a lot from patients' experiences in these programs."

About Mateon Therapeutics

Mateon was created by the recent reverse merger with Oncotelic which became a wholly owned subsidiary of Mateon Therapeutics Inc. (OTCQB: MATN) creating an immune-oncology company dedicated to the development of first in class RNA therapeutics as well as small molecule drugs against cancer. OT-101, the lead immune-oncology drug candidate of Mateon, is a first-in-class RNA therapeutic targeting TGF beta that exhibited single agent activity in some relapsed/refractory cancer patients in clinical trial settings. The founding team of Oncotelic was responsible for the development of Abraxane as chemotherapeutic agents for breast, lung, melanoma, and pancreatic cancer. Abraxane was approved in 2005 and has \$1B in sales annually and Cynviloq, a next generation Abraxane, was acquired by NantPharma for \$1.3B. Mateon will leverage its deep expertise in oncology and RNA therapeutic drug development to improve treatment outcomes and survival of cancer patients. For more information, please visit www.oncotelic.com or www.mateon.com.

About WideTrial Inc.

WideTrial is clinical data company in Silicon Valley serving as a specialist, third-party sponsor of data-generating cohort Expanded Access programs (EAPs). More information is available at www.widetrial.com.

About PointR Data Inc.

PointR is a revenue generating stage AI company with a revolutionary cluster-computer platform for AI that crunches machine learning models at a fraction of the power and budget of mainstream computing. It provides for an AI computing platform for pharmaceutical and healthcare verticals including blockchain support for clinical and manufacturing where data integrity and security are of utmost importance. PointR is composed of a team of seasoned Silicon Valley executives. PointR CEO, Saran Saund has been founder, CEO and GM at several startups and public companies. He has returned significant value to shareholders in his startups. Chief technology officer, Burcak Beser has been founder and CTO of several successful private and public companies with over 144 patents during his career. For additional information please visit www.pointr.ai

About Mateon's Lead Product Candidate, OT-101

High-grade gliomas (HGG) are characterized by a T-cell exhaustion signature and pronounced T-cell hyporesponsiveness of their tumor microenvironment (TME). Transforming growth factor beta 2 (TGFB2) has been implicated as a key contributor to the immunosuppressive landscape of the TME in HGG. OT-101, a TGFB2-specific first-in-class RNA therapeutic designed to abrogate the immunosuppressive actions of TGFB2. In a completed Phase 2 clinical study, OT-101 exhibited clinically meaningful single-agent activity and induces durable complete and partial responses in recurrent and refractory adult HGG patients, including young adults with GBM or AA. Efficacy was also demonstrated in treatment failure pancreatic cancer patients and melanoma patients, suggesting that OT-101 is effective among all solid tumors overexpressing TGF-beta.

Mateon's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Words such as "may", "expect", "anticipate", "hope", "vision", "optimism", "design", "exciting", "promising", "will", "conviction", "estimate," "intend," "believe" and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about future plans, the progress, timing, clinical development, scope and success of future clinical trials, the reporting of clinical data for the company's product candidates and the potential use of the company's product candidates to treat various cancer indications. Statements concerning the anticipated completion of the proposed merger, the anticipated success of the PointR technology, or the benefits expected to be gained from the merger are all forward-looking statements. Each of these forward-looking statements involves risks and uncertainties and actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. These risks are not exhaustive, the company faces known and unknown risks, including the risk factors described in the company's annual report on Form 10-K filed with the SEC on April 10, 2019 and in the company's other periodic filings. Forward-looking statements are based on expectations and assumptions as of the date of this press release. Except as required by law, the company does not assume any obligation to update forward-looking statements contained herein to reflect any change in expectations, whether as a result of new information future events, or otherwise.

Contact Information:

Mateon
Amit Shah
Email: ashah@oncotelic.com

PointR Data
Saran Saund
Email: saran@pointr.ai

WideTrial
Ian Manger, Ph.D.
Email: ian.manger@widetrial.com
