Proposal for Lucid Psycheceuticals

Manufacture of Lucid-201 Drug Substance for Phase 1 Clinical Studies

[REDACTED]

Covar Pharmaceuticals Inc.

7/20/2021

Table of Contents

Introduction

Covar Pharmaceuticals Inc. (Covar) will manufacture, under the direction of Lucid Psycheceuticals ("Lucid" or "Client"), Non-GMP and GMP Lucid-201 for use in pre-clinical and Phase 1 clinical trials, respectively. Lucid-201 is a Controlled Substance listed under the Controlled Drugs and Substances Act, Canada.

Scope of Work

The scope of work involves:

- Phase appropriate analytical method development
- Development and optimisation of synthesis route at up to 20 g scale.
- API characterization and polymorph screening (assuming salt screening is not required)
- Process scale-up to maximum batch size of 300 g
- Manufacture of non-GMP batch for non-clinical studies
- GMP batch manufacture

[REDACTED]

Environmental, Health and Safety

The Environmental, Health and Safety (EH&S) requirements for handling the Active Pharmaceutical Ingredient (API) and drug related substances, if required, will be provided by the Client.

Synthesis Route Development and Optimisation

[REDACTED]

Covar will perform (under the direction of the Client) process research and development to develop and optimise each processing step for the synthesis of Lucid-201 (batch size 20 – 200 g). Areas of investigation may include but are not limited to solvent selection, reagent sequence of addition, process changes to reduce ingredient expense, yield enhancement, and impurity identification/profile development. Materials will be evaluated by [REDACTED] [REDACTED] to ensure a safe scale-up.

Each processing step will be studied separately. A final recrystallization or purification step may be performed to obtain acceptable API for GLP animal studies (if needed) or clinical studies.

[REDACTED]

Testing performed during the synthesis route development and optimisation may include:

[REDACTED]

[REDACTED] assessment will be conducted under long term and accelerated ICH storage conditions for the following:

- [REDACTED]

API Characterization and Polymorphic Screening

[REDACTED]

A polymorphic screening study will also be conducted if needed for formulation development.

Process Scale Up

Covar will perform process research and development to define phase appropriate operations for optimizing the existing transformations or to identify suitable alternative conditions [REDACTED]

[REDACTED]

[REDACTED]

Analytical Method Development and Validation

Analytical method development will be performed to support testing of starting materials, intermediates, and the manufacture of drug substance. The following is a list of anticipated analytical activities:

Material	Method Development Activities	Method Validation/Verification Activities	GMP Documentation
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

	[REDACTED]	[REDACTED]	[REDACTED]

*All starting materials will be received by appearance, identity (FTIR), CofA and BSE/TSE statements.

- AAM = Authentic Analytical Material (limited qualification)
    - Qualified based on intended use. Typical qualification tests include but are not limited to: appearance, HPLC or FTIR.
- Development of scientifically sound achiral purity methods involve the following:
    - Define expected impurities based on available information (e.g. synthetic route, batch history, etc.) and with input from the Client.
    - Select detection techniques based on impurity properties (UV as standard).
    - Method development and optimization includes evaluation of linearity, range, accuracy, precision, and quantitation limit.
    - Methods for starting materials and intermediates may be separate per material or may accommodate multiple materials in a single method.
- The drug substance methods will be subjected to a phase appropriate validation/qualification using a subset of ICH Q2(R1) as guidance. The qualification/validation activities will be performed under protocol, with predetermined acceptance criteria. The parameters included are specificity, linearity, range, accuracy, precision, detection limit, and quantitation limit, as appropriate for the type of method.
- In-Process Control (IPC) Methods
    - One IPC method for each of the GMP synthetic transformations will be evaluated
- Other attributes to be tested may include appearance, residue on ignition (ROI), and DSC, none of which require verification prior to testing.

The following analytical methods will be validated for test of Phase 1 clinical API:

[REDACTED]

[REDACTED]

GMP Batch Manufacture

To support the manufacture of **Lucid-201** under GMP conditions, the following analytical development activities will be performed:

[REDACTED]

Upon completion of manufacture, the product will be tested and released using the qualified methods [REDACTED]

[REDACTED]

[REDACTED]

Project Management

A project team and project manager will be assigned once the proposal is approved. A kickoff meeting will be held between the Client and the project team to introduce the team members, further develop the project plan, and define the logistics to execute the project. The project will be coordinated by the project manager. The project manager is responsible for scheduling regular team meetings, project updates, strategic planning, invoicing and cost/scope revisions.

High-Level Timeline

[REDACTED]

Budget Estimate

[REDACTED]

[REDACTED]

Signatures

Lucid Psychceuticals

By: ***(Signed) Lucid Psycheceuticals***

Name: _____

Title: _____

Date: September 30, 2021

Covar Pharmaceuticals Incorporated

By: ***(Signed) Covar Pharmaceuticals Incorporated***

Name: _____

Title: _____

Date: Oct. 1, 2021

Terms and Conditions

Services

Covar Pharmaceuticals Incorporated (Covar) agrees to perform the pharmaceutical development services described in the Project Scope ("**Services**") of this **Agreement**. Services will be performed in the Preferred Provider Laboratories (**Provider**) selected by **Covar.** Unless otherwise stated the **Services** will be non-GMP.

Parties must agree on Changes to the Services ("**Changes**").

Minor Changes will be confirmed by electronic mail, or other written document. Significant Changes (such as a request by the **Client** to change the Project Scope) will be confirmed by a Change of Scope **Agreement**.

Payment

Client will pay **Covar** for the **Services**.

Client will pay **Covar** a refundable deposit equal to [REDACTED] of the estimated cost provided in this proposal. The deposit will be used for the final payments of the project.

Services Covar may issue an invoice upon completion of each milestone set out in the Budget Summary or revised Budget Summary in Changes.

Covar invoice will be due and payable within 30 days of the date of the invoice.

Interest on past due accounts will accrue at a rate of 1.5% per month.

In the event that payment in full is not received by **Covar** within thirty (30) days of **Client**'s receipt of the data and results, this **Agreement** may be terminated at **Covar**'s sole discretion and all right and title to the data and results.

Ownership of Data

Client will own all data and information specifically and directly arising from the provision of the Services, and as such **Covar** will have no claim on any intellectual property that may be derived from any such data and information.

Intellectual Property

The term "Intellectual Property" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, trade secrets, inventions, copyright, industrial designs and know-how.

For the term of this Agreement, Client hereby grants to Covar, a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Covar must use in order to perform the Services.

All Intellectual Property generated or derived by Covar in the course of performing the Services, to the extent it is specific to the development, manufacture, use and sale of the Client's Product that is the subject of the Services, will be the exclusive property of Client.

All Intellectual Property generated or derived by Covar while performing the Services which is not specific to, or dependent upon, Client's Product and which has application to manufacturing processes or formulation development of drug products or drug delivery systems will be the

exclusive property of Covar. Covar hereby grants to Client, a non-exclusive, paid-up, royalty-free, transferable license of the Intellectual Property which Client may use for the manufacture of Client's Product.

Confidentiality

The confidentiality agreement entered into between the parties will apply to all confidential information about the parties and the Services to be conducted under this **Agreement** and the Confidentiality **Agreement** is deemed to be incorporated herein by reference. If the Confidentiality **Agreement** expires or terminates prior to the expiration or termination of this **Agreement**, then the terms of the Confidentiality **Agreement** will nonetheless continue to govern the parties' obligations of confidentiality for the term of this **Agreement** and for five years thereafter. **Covar** shall have the right to disclose confidential information hereunder to its Preferred Providers solely for the purpose of performing the Services. **Covar** represents that it has entered into confidentiality **Agreement**s with each Preferred Provider consist with the terms hereof.

Providers shall hold in confidence and not disclose or use for any purpose other than for the provision of the Services any "**Confidential Information**" provided by **Client**. "Confidential Information" means any information provided by the **Client** to **Providers** in confidence and any **Client** samples and/or materials associated with the Services, and shall further include any information and all related data and information generated pursuant to the provision of the Services.

Confidential Information shall not include or otherwise encompass any information and materials which:

- are part of the public domain, or become part of the public domain through no fault of **Providers**;
- are obtained from a third party who is not under a duty of confidentiality respecting the Confidential Information and said third party has a legal right to disclose such information;
- are identified by the **Client** as no longer constituting Confidential Information of the **Client**;
- are already known at the time of disclosure by **Client** to **Providers**, as can be demonstrated by written or other records/information; or
- are developed independently by **Providers** without access to the Confidential Information of the **Client**, as can be demonstrated by written or other records/information.

In the event that **Covar** is required to disclose **Client** Confidential Information by law or an order of a court, tribunal or government agency, **Covar** shall promptly notify **Client** and give **Client** a reasonable opportunity to seek a confidentiality order or take other appropriate action in respect of the proposed disclosure.

This obligation of confidentiality in respect of any particular Confidential Information shall survive for a period of **three (3) years** from the earlier of (i) the full and final provision of the specific Services associated with the particular Confidential Information, or (ii) the expiration or earlier termination of this **Agreement**.

Non-Compete

Covar will not provide Pharmaceutical Development Service to another organisation to develop pharmaceutical products for Lucid-201 or structurally related molecules for the intended treatment of diseases using Lucid-201 without prior written consent from the Client. This non-compete commitment and exclusive development service from **Covar** to the **Client** for Lucid-

201 will be enforced during the provision of the services and 6 months after termination or completion of the services, provided that all outstanding invoices have been paid on or before their respective due dates

Term and/or Termination

Notwithstanding, a Party may earlier terminate this **Agreement** upon the provision of thirty (30) day notice to the other Party, and the Parties shall immediately cease all unnecessary activities and shall cooperate to minimize all costs associated with this cessation/termination of activities associated with the provision of said Services.

Either party may terminate this **Agreement** if a party is in material breach of any part of this **Agreement** and that party fails to remedy the breach within 30 days after receiving notice of the breach from the non-breaching party.

Client may terminate this **Agreement** upon 5 days prior written notice for any business reason.

Covar may terminate the **Agreement** if the **Client** requests to reschedule any part of the Services beyond 180 days.

Upon completion or expiry of the **Agreement** or if the **Client** terminates the **Agreement** for any business reason or if **Covar** terminates the **Agreement** because of: (i) **Client**'s failure to cure any default within the 30 day notice period; or (ii) **Client** rescheduling any part of the Services beyond the 180 days, then **Client** will pay to **Covar** any fees and expenses due to **Covar** and any additional costs incurred by **Covar** with the **Services**.

Client will arrange for the pickup from the **Covar** site of all materials owned by **Client** within ten days after the earlier of the completion, or termination of this **Agreement**.

Shipping of API and Materials

Client will, at its expense, supply **Covar** with sufficient quantities of API for **Covar** to perform the Services. For all shipments of API and materials from **Client** to **Covar**, **Client** will pay all costs including transportation, import duties and taxes. All shipments of API will be accompanied by appropriate Safety Data Sheet (e.g. MSDS).

For import of API, **Client** or **Client**'s broker will be the "Importer of Record." **Client**'s obligation will include obtaining the proper release of API from the local customs and health authorities.

For shipments (if applicable) of **Client**'s Product or **Client**'s API, the **Client** will pay all transportation costs and also bear the risks for bringing the goods to their final destination.

Indemnity

Client shall indemnify and save harmless **Covar** against all costs, actions, suits, claims, losses or damages and for all other matters arising out of its (i.e **Client**'s) use or any other exploitation of the data, results, conclusions, and products derived therefrom, arising out of, or resulting from, this **Agreement** (and any intellectual property associated therewith), except to the extent that such were caused by **Covar**'s gross negligence, willful misconduct or material breach of this **Agreement**.

Covar will defend, indemnify and hold the **Client** harmless against **Covar** of any of its obligations or warranties under this **Agreement** except to the extent that these Losses are determined to have resulted from the negligence or willful misconduct of **Client**.

Limitation of Liability

Covar (and its directors, officers, employees, staff members, students, research trainees and agents) shall not be liable for any direct, indirect, consequential, or other damages suffered by **Client** or any others resulting from the use of the data, results or conclusions, and any products and intellectual property associated therewith, conceived, discovered, or otherwise premised on, or developed under or as a result of, or consequential to, this **Agreement**. The entire risk as to any use of said data, conclusions or results (and any products and intellectual property associated therewith), and the design, development, manufacture, offering for sale, sale, or other disposition and/or performance of the data, results, conclusions and products arising therefrom (and any intellectual property associated therewith) is assumed entirely by **Client**, without any legal or equitable recourse to **Covar**

If **Covar** fails to materially perform any part of the Services in accordance with the terms of this **Agreement**, **Covar** may repeat that part of the Service at **Covar**'s costs if **Client** supplies the API. Under no circumstances whatsoever will **Covar** reimburse **Client** for the cost of the API. Under no circumstances whatsoever will either party be liable to the other in **Agreement**, tort, negligence, breach of statutory duty or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or (ii) any other liability, damage, cost or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of the damages.

No Warranty

Covar makes no warranty of any kind, either expressed or implied, by fact or law, other than those expressly set forth in this **Agreement**. **Covar** makes no warranty for any particular results from the performance of the services or with respect to any data or information generated therefrom, or of fitness for a particular purpose or warranty of merchantability for the **Client**'s product.

Disputes

All negotiations under this provision shall be considered confidential and shall be treated as compromise and settlement negotiations and deemed to be "off the record" and without prejudice.

General Provisions

This **Agreement** shall be construed according to the laws of the Province of Ontario and the federal laws of Canada applicable therein.

Each provision of this **Agreement** shall be deemed separate, severable and distinct. If any part of any provision of this **Agreement** is found by a court to be invalid, illegal or unenforceable in any way, the finding shall not limit or affect the validity, legality or enforceability of the remaining provisions.

For the purposes of this **Agreement** and all services to be provided under it, each Party shall be deemed to be an independent **Agreement** or and not an agent or employee of the other Party. No Party shall have the authority to make any statements, representations or commitments of any kind, or take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing.

Except as otherwise required by law, neither Party shall, without the consent of the other Party, (i) use the name(s), logo(s), trade-mark(s) or trade-name(s) of the other Party in connection with any

products, publicity, promotion, news release, advertising or similar public statements in respect of the **Agreement** and the Services provided, **and** (ii) make any other public disclosure in respect of this **Agreement** and its subject matter. Notwithstanding, **Covar** may disclose the general subject matter and monies received further to this **Agreement** without any further consent of **Client**.

This **Agreement**) constitutes the entire **Agreement** and understanding between the Parties and supersedes any prior **Agreement**s between or among the Parties with respect to the **Services**.

This **Agreement** may be signed in separate counterparts and delivered by mail, facsimile or electronically, and, when so signed and delivered, all the counterparts will together constitute one and the same instrument which is deemed to be an original.

Neither this **Agreement**, nor any of either party's rights hereunder, may be assigned or otherwise transferred by either party without the prior written consent of the other party, which consent will not be unreasonably withheld.

Except for payment obligations, neither party will be responsible for delay or failure in performance resulting from acts beyond the reasonable control and without the fault or negligence of the party, including, but not limited to, strikes or other labour disturbances, wars, riot, crime, communicable disease outbreaks, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, power or regulation compliance of any government or act of God.

Any termination or expiration of this **Agreement** will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this **Agreement**.