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):
October 24, 2022

CINGULATE INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40874**	**86-3825535**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

1901 W. 47th Place
Kansas City, KS 66205
(Address of principal executive offices) (Zip Code)

(913) 942-2300
(Registrant's telephone number, including area code)

(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 each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.0001 per share	CING	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Warrants, exercisable for one share of common stock	CINGW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 October 24, 2022, Cingulate Inc., through its wholly-owned subsidiary, Cingulate Therapeutics LLC (collectively, the "Company"), entered into a Maser Services Agreement (the "Agreement") with Societal CDMO, Inc. ("Societal").

The Agreement governs the general terms under which Societal, or one of its affiliates, will provide manufacturing services as specified by the Company at Societal's Gainesville, Georgia manufacturing facility. Pursuant to the Agreement, the Company and Societal will enter into various Statements of Work to set forth the services to be performed by Societal and the payments to be made by the Company for each project (each, a "Statement of Work"). Each Statement of Work will be governed by the terms of the Agreement, unless expressly modified in such Statement of Work.

The Agreement has an initial term that expires on October 24, 2027 or such later date as required to complete a Statement of Work (the "Initial Term") and will renew automatically thereafter for successive twelve (12) month periods (a "Renewal Term") unless terminated by either party at least twelve (12) months (if prior to the successful completion of process validation batches for the first product) or twenty-four (24) months (after successful completion of validation batches for the first product) prior to the end of the Initial Term or any Renewal Term. The Company may terminate any Statement of Work or the Agreement upon ninety (90) days prior, written notice. Societal may terminate a Statement of Work due to certain delays or inactivity or if the services provided under such Statement of Work can't be performed in accordance with applicable regulatory requirements; provided, that Societal shall use commercially reasonable efforts to engage in meaningful discussions with the Company prior to any such termination. Societal may terminate the Agreement upon six (6) months prior, written notice if all Statements of Work have been terminated. Either party may terminate any Statement of Work or the Agreement for material, uncured breaches or in the event of the other party's bankruptcy.

The Agreement contains representations, warranties and indemnity obligations customary for agreements of this type.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, which has been filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company has redacted certain confidential portions of the Agreement because such confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Item 7.01. Regulation FD Disclosure.

On October 24, 2022, the Company issued a press release announcing the Agreement with Societal and providing a clinical update. A copy of the press release is furnished as Exhibit 99.1 and incorporated by reference.

The Company updated its investor presentation to be used at investor conferences and in investor meetings. A copy of the investor presentation is furnished as Exhibit 99.2 and incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1*	Master Services Agreement between Cingulate Therapeutics LLC and Societal CDMO, Inc., dated October 24, 2022
99.1	Press Release dated October 24, 2022
99.2	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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.

CINGULATE INC.

Dated: October 25, 2022

By: */s/ Shane J. Schaffer*
Name: Shane J. Schaffer
Title: Chief Executive Officer

Exhibit 10.1

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

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "Agreement") is made as of October 24, 2022 (the "Effective Date") by and between Societal CDMO, Inc., a Pennsylvania corporation, with its principal place of business at 1300 Gould Dr., Gainesville, GA 30504 (collectively with each of its subsidiaries and affiliates, including IriSys, LLC and Recro Gainesville LLC, "Societal CDMO") and Cingulate Therapeutics LLC, a Delaware limited liability company with its principal place of business at 1901 W. 47th Place, 3rd Floor, Kansas City, Kansas 66205 (the "Client"). Societal CDMO and Client may be individually referred to herein as a "Party" or may be collectively referred to herein as the "Parties".

RECITALS

WHEREAS, Societal CDMO is in the business of providing certain pharmaceutical development and/or technology transfer services, as may be described from time to time in one or more Statements of Work.

WHEREAS, Client desires to obtain from Societal CDMO certain services from time to time under the terms and conditions set forth herein, such services up to but not including commercial production.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below, the Parties, intending to be legally bound, hereby agree as follows.

1. DEFINITIONS: The following terms shall have the meanings set forth below:

1.1. "Acceptance Criteria" means the tests and other factors set forth in the Master Batch Record and analytical and quality documents.

1.2. "Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended to date and as may be further amended from time to time during the Term, and the regulations promulgated with respect thereto.

1.3. "Affiliate" means any person, firm, trust, partnership, corporation, company or other entity or combination thereof which, directly or indirectly, (i) controls a Party, (ii) is controlled by a Party, or (iii) is under common control with a Party. For the purposes of this definition, the terms "control" and "controlled" means ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, partnership, corporation, company or other entity or combination thereof or the power to direct the management of such person, firm, trust, partnership, corporation, company or other entity or combination thereof.

1.4. "Agreement" shall have the meaning set forth in the preamble.

1.5. "API" means the active pharmaceutical ingredient of a drug product.

1.6. "Bailed Property" has the meaning set forth in Section 5.1(a).

1.7. "Batch" means a specific quantity of a drug or other material that is intended to have uniform character and quality within specified limits and is produced according to a single manufacturing order during the same cycle of manufacture.

1.8. "Batch Record" means the production record pertaining to a Batch.

1.9. "Business Day" means any day except Saturday, Sunday or any other day on which commercial banks located in Atlanta, Georgia are authorized or required by law to be closed for business.

1.10. "Certificate of Analysis" means the document for API, Materials, work-in-process product or Product prepared by Societal CDMO, reporting the results of testing conducted by Societal CDMO.

1.11. "cGMP" means, as applicable, then-current good manufacturing practices as described in: (i) Parts 210 and 211 of Title 21 of the United States Code of Federal Regulations; (ii) Commission Directive (EU) 2017/1572 (art. 2); and (iii) Division 2 of Part C of the Food and Drug Regulations (Canada); together with current final industry-accepted Health Canada, FDA, and European Medicines Agency guidance documents pertaining to manufacturing and quality control practice, all as updated, amended, and revised from time to time.

1.12. "Change Order" means a written document executed by authorized representatives of both Parties which alters or modifies a Statement of Work.

1.13. "Client" shall have the meaning set forth in the preamble.

1.14. "Client Capital Requirements" shall have the meaning set forth in Section 6.6.

1.15. "Client Indemnitees" shall have the meaning set forth in Section 9.1.

1.16. "Client's Intellectual Property" means all Intellectual Property rights, worldwide, specific to any Product or any generic version thereof or the development, manufacture, testing, storage packaging, use and/or sale of any Product, including, but not limited to, any analytical methods, certified reference standards, impurity markers, manufacturing, storage, packaging processes and procedures, specifications, batch records and control documents, raw materials and other materials, data or other information specific to any Product (in each case, whether provided by or on behalf of Client to Societal CDMO in connection with this Agreement, or developed by or on behalf of Societal CDMO, any of its Subcontractors or Affiliates or any of its or their respective personnel in connection with this Agreement), and further including any Client Inventions.

1.17. "Client Inventions" shall have the meaning set forth in Section 8.3.

1.18. "Deficiencies" shall have the meaning set forth in Section 12.3.

1.19. "Duties" shall have the meaning set forth in Section 4.3.

1.20. "Effective Date" shall have the meaning set forth in the preamble.

1.21. "Encumbrance" means any charge, claim, community property interest, pledge, condition, equitable interest, lien (statutory or other), option, security interest, mortgage, easement, encroachment, right of way, right of first refusal, or restriction of any kind, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership.

1.22. "Finished Product" means Products that are Manufactured in accordance with the applicable Product Specifications, cGMPs and other, Regulatory Standards, and the terms and conditions of this Agreement, the Quality Agreement and the applicable Statement of Work, and released to Client in accordance with Section 2.10.

1.23. "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.24. "Governmental Authority" means any federal, state or other governmental department, governmental authority, or judicial or administrative body, including, but not limited to, the FDA.

1.25. "Initial Term" shall have the meaning set forth in Section 7.1.

1.26. "Inspection Period" shall have the meaning set forth in Section 2.12.

1.27. "Intellectual Property" shall include, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade names, trade dress, Trade Secrets, Inventions, discoveries, improvements, modifications, work product, works-in-progress, data, records, reports, analytical methods, other methods and procedures, copyright, industrial designs, data and know-how and all other intellectual and industrial property rights of any sort throughout the world now known or hereafter recognized.

1.28. "Inventions" means any idea, concept, innovation, invention, improvement, development, discovery, technology, computer program, device, work of authorship, reports, records, certificates, statements, data, formula, compound method, know-how, process, method, technique, protocol or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable.

1.29. "Losses" shall include all Third Party actions, causes of action, costs (including reasonable legal fees), claims, damages, liabilities and expenses.

1.30. "Manufacture" or "Manufacturing" means the manufacture, filling, finishing, sampling, testing, labeling, packaging, release, storage, shipping and quality control of the Finished Products in accordance with the applicable Product Specifications, cGMPs, Regulatory Standards, and the terms and conditions of this Agreement, the Quality Agreement and the applicable Statement of Work.

1.31. "Manufacturing Facility" means Societal CDMO's premises and equipment located at any facility where manufacturing, packaging, testing or storing of Product takes place.

1.32. "Master Batch Record" means a master production and control record containing a written description of the procedure to be followed for processing a Batch of Product including, but not limited to, a complete list of all active and inactive ingredients, components, weights and measures, equipment setup and run parameters, descriptions of drug product containers, closures, packaging materials, and labeling and complete specifications for each, within the meaning of 21 CFR part 211.186, or its successor as in effect from time to time.

1.33. "Materials" shall include all materials and supplies required to perform the Services, including API, certain analytical columns, reagents, excipients and packaging components.

1.34. "NDA" means a New Drug Application as defined in the Act.

1.35. "Nonconforming Products" means any Products produced by Societal CDMO that: (a) do not conform to the Product Specifications for such Product; or (b) exceed the quantity of Products ordered by Client pursuant to this Agreement or Statement of Work. Where the context requires, Nonconforming Products are deemed to be Products for purposes of this Agreement.

1.36. "Pass-Through Costs" means any fees, costs or expenses incurred by Societal CDMO from Third Parties in connection with the acquisition of Materials and supplemental services necessary to perform the Services, in each case to the extent set forth in the applicable Statement of Work or otherwise approved by Client in writing.

1.37. "Person" means a corporation, association, joint venture, partnership, trust, business, individual, government or political subdivision thereof, or any Governmental Authority.

1.38. "Product" means the drug product(s) covered by this Agreement and produced as contemplated in and pursuant to the Product Description.

1.39. "Product Description" means those documents attached to a Statement of Work, which provide specific details about each Product to be produced for Client by Societal CDMO under such Statement of Work.

1.40. "Product Specifications" means the applicable quality control, quality assurance and other requirements, procedures, guidelines and specifications for the manufacturing, packaging, labeling, testing, handling, dating and storage of a Product, each as set forth in the applicable Registration for such Product or as may be required pursuant to any Regulatory Standards, and further including the specifications attached to or referenced in the applicable Statement of Work, and as may be amended from time to time as required by any Regulatory Standards or by the mutual written agreement of the parties

1.41. "Product Warranty" shall have the meeting set forth in Section 9.5(a).

1.42. "Quality Agreement" means the Quality Agreement for Contract Drug Manufacturing executed between Client and Societal CDMO for any Product, which specifies the respective responsibilities for quality control and quality assurance activities consistent with cGMPs with respect to the activities undertaken in accordance with of this Agreement.

1.43. "Registrations" means all permits, licenses, approvals and authorizations granted by any Governmental Authority with regard to any Product, including, without limitation, any NDAs for any Product.

1.44. "Regulatory Standards" means (a) any and all permits, licenses, filings and certifications required by the FDA, including, but not limited to cGMPs (b) any laws, rules, regulations and standards of any Governmental Authority, (including, without limitation, the Environmental Protection Agency ("EPA"), the Occupational Safety and Health Administration ("OSHA"), the Drug Enforcement Administration ("DEA") and state and local authorities), that apply to the Manufacturing Facilities or Societal CDMO's processing, storage handling, or shipment of Materials or Products.

1.45. "Release Date" means the date on which all Release Documents have been signed by Societal CDMO and approved by Client in accordance with Section 2.10 for Finished Products that are finished (including, but not limited to, in final packaging) and ready for delivery.

1.46. "Release Documents" means, with respect to a Batch of Finished Product, the Certificate of Analysis or Conformance and any other documents identified in the Quality Agreement or applicable Statement of Work as documents that will be provided to Client by Societal CDMO upon Finished Product release.

1.47. "Renewal Term" shall have the meaning set forth in Section 7.1.

1.48. "Societal CDMO" shall have the meaning set forth in the preamble.

1.49. "Societal CDMO Indemnitees" shall have the meaning set forth in Section 9.1.

1.50. "Societal CDMO's Property" shall have the meaning set forth in Section 5.4.

1.51. "Societal CDMO's Intellectual Property" means all Intellectual Property owned by or licensed to Societal CDMO, including any of Societal CDMO's Intellectual Property which is not developed in connection with this Agreement but which is used in the design, production, and manufacturing of the Products (but, in each case, excluding any of Client's Intellectual Property).

1.52. "Services" shall have the meaning set forth in Section 2.1.

1.53. "Statement of Work" shall refer to the document in a form approved by Societal CDMO and set forth on Exhibit A-1, which details the particular Services to be performed for each project. Each Statement of Work shall be attached to this Agreement as sequentially numbered exhibits (e.g., Exhibit A-2, Exhibit A-3, etc.).

1.54. "Subcontractors" shall have the meaning set forth in Section 2.3.

1.55. "Supplied Items" shall have the meaning set forth in Section 11.1.

1.56. "Term" shall have the meaning set forth in Section 7.1.

1.57. "Third Parties" means any Person except a Party or an Affiliate of a Party.

1.58. "Trade Secret" means a formula, practice, process, design, instrument, pattern, commercial method, or compilation of information not generally known or reasonably ascertainable by others by which Client can obtain an economic advantage over competitors or customer.

1.59. "Work-in-Process" means all Products that Societal CDMO has begun to Manufacture into Finished Products, but which have not yet satisfied the requirements of Section 2.9 or Section 6.6.

2. TERMS OF SERVICES

2.1. Statement of Work. During the Term of this Agreement, Societal CDMO shall provide services as described in a Statement of Work (the "Services"). Societal CDMO may conduct more than one project in connection with this Agreement, as mutually agreed upon by the Parties and set forth in a written Statement of Work for each such project, which Statement of Work shall be signed by both Parties prior to commencement of the Services. Each Statement of Work shall include the following information: (i) a description of the project, (ii) the budget and payment schedule for the project, (iii) the timing or schedule for the project, and (iv) any other relevant information. Each Statement of Work shall be incorporated by reference into this Agreement and shall be construed under the terms of this Agreement and nothing contained in a Statement of Work shall be construed to amend or modify any provision of this Agreement. To the extent the terms of any Statement of Work, or any other writing between the Parties (with the exception of a formal amendment to this Agreement), conflicts with the terms of this Agreement, the terms of this Agreement shall control.

2.2. Changes or Modifications. Any alteration, modification or other change to a Statement of Work will require execution by the Parties of a Change Order. Each Change Order will set forth in sufficient detail the changes in Services and/or terms (e.g., term, timeline, budget, payment schedule, deliverables, key personnel and/or overall level of responsibility), or other alteration to the Statement of Work and each Change Order will be deemed attached to such Statement of Work and made a part thereof. Any Change Order will become effective only upon the date of execution thereof by both Parties, unless the Change Order specifically sets forth a different effective date. Both Parties agree to act in good faith to promptly identify, review and, if agreed by the Parties, execute Change Orders.

2.3. Subcontractors; Use of Third-Party Vendors. Societal CDMO may employ or engage the service of such subcontractors as Societal CDMO deems necessary to perform the Services required by this Agreement (the "Subcontractors"), subject to Client's prior, written approval in each case. Societal CDMO acknowledges and agrees that it shall be fully liable for all acts or omissions, or other violations of this Agreement, relating to the use of such Subcontractors. Client further acknowledges and agrees that Societal CDMO may acquire Materials or supplemental services through Third Parties in accordance with the terms of the applicable Statement of Work, and that Client agrees to pay any Pass-Through Costs related to the use of such Third Parties. Notwithstanding the foregoing, Societal CDMO will have no liability to the extent arising from the performance of the Services by Subcontractor: (i) that are chosen or requested specifically by Client (except to the extent Societal CDMO is grossly negligent or in breach of this Agreement in its direction or oversight of such Subcontractor); or (ii) if the Subcontractor is following the direct instructions of Client.

2.4. Manufacturing Compliance Requirements. Societal CDMO shall Manufacture the Products in accordance with the applicable Product Specifications, cGMPs, Regulatory Standards, and the terms and conditions of this Agreement, the Quality Agreement and the applicable Statement of Work.

2.5. Compliance with Laws. Societal CDMO represents, warrants and covenants that it: (i) has and shall maintain at all relevant times the appropriate registrations, licenses and any other governmental authorizations required to enable it to lawfully and properly perform the Services under this Agreement; (ii) shall perform all of its obligations under this Agreement in a professional and workmanlike manner and in accordance with generally accepted standards of the pharmaceutical manufacturing industry, this Agreement, the Quality Agreement, the applicable Statement of Work, and Societal CDMO's SOPs to the extent not inconsistent with this Agreement, the Quality Agreement, the applicable Statement of Work, cGMPs and other Regulatory Standards or the Product Specifications.

2.6. Product Specifications. Each Statement of Work will include or reference (a) the Product Specifications, (b) the API and specifications thereof; (c) the excipients and specifications thereof; (d) any special requirements, including required sources, for the procurement of API and Materials; (e) the packaging and labeling specifications; (f) any special equipment Societal CDMO is required to purchase to manufacture a Product; and any equipment and process parameters and set points.

2.7. Master Batch Record. Societal CDMO shall prepare and maintain the Master Batch Record for the manufacture of each Product at its Manufacturing Facility. Any change to the Master Batch Record requires the Client's prior, written approval.

2.8. Manufacturing Process. All API and other Materials will be received and held in quarantine by Societal CDMO until testing has been reviewed and approved by Societal CDMO's Quality Assurance Department and all release documents have been produced with respect to such API and other Materials. On receipt of the signed Master Batch Record from Client, Societal CDMO shall process the API and Materials at the Manufacturing Facility in accordance with the Master Batch Record, any and all applicable Regulatory Standards, the Acceptance Criteria, cGMPs, the Product Specifications, the Quality Agreement, Societal CDMO's quality assurance and quality control practices and the other requirements of this Agreement and the applicable Statement of Work.

2.9. Product Release. Upon submission of agreed upon Product samples for final testing, Societal CDMO shall prepare the Release Documents specific to each Batch of Finished Product and shall submit them, at Societal CDMO's cost, to Client no later than seven (7) Business Days following such final testing. Release Documents will not be considered final unless and until Societal CDMO has performed a quality assurance review thereof. Client shall approve or reject the Release Documents within five (5) Business Days from receipt of Release Documents. If Client approves Release Documents, Client shall authorize Societal CDMO to release the Batch of Product and Societal CDMO shall issue the Certificate of Analysis with the Release Date.

2.10. Packaging and Labeling. Societal CDMO shall properly pack, label and ship Product as instructed by Client and otherwise in accordance with applicable Product Specifications, cGMPs, Regulatory Standards, and the requirements of this Agreement, the Quality Agreement and the applicable Statement of Work. Label template will be provided by the Client. Societal CDMO shall provide Client with shipment documentation showing Societal CDMO's identification number for the Product, the quantity of pieces in shipment, the number of cartons or containers in shipment, Societal CDMO's name, the bill of lading number, and the country of origin.

2.11. Inspection. Products are subject to Client's inspection and approval or rejection notwithstanding Client's prior receipt of or payment for the Product. Client shall have a reasonable period of time, not to be less than ten (10) Business Days following receipt of the Product at Client's final destination ("Inspection Period"), to inspect all Product received under this Agreement and to inform Societal CDMO, in writing, of Client's rejection of any Nonconforming Product. Client may return to Societal CDMO any or all units of rejected Product that constitute Nonconforming Product because they exceed the quantity stated in the Statement of Work by more than five percent (5%). If Client rejects any other Nonconforming Product, Client may elect to require Societal CDMO, at Societal CDMO's sole cost, subject to Section 9.4(b), to replace the rejected Product at the location specified by Client (which may include Societal CDMO's location, Client's location or the location of a third party) without limiting the exercise by Client of any other rights available to Client under this Agreement or pursuant to applicable Law. All returns of Nonconforming Product to Societal CDMO are at Societal CDMO's sole risk and expense. Product that is not rejected within the Inspection Period will be deemed to have been accepted by Client; provided, however, that Client's acceptance of any Product will not be deemed to be a waiver or limitation of Societal CDMO's obligations pursuant to this Agreement (or any breach thereof), including those obligations with respect to Societal CDMO's Product Warranty and Societal CDMO's duty to indemnify Client.

3. CERTAIN OBLIGATIONS OF SOCIETAL CDMO

3.1. Quality.

(a) Societal CDMO shall at a minimum meet Client's quality standards for the Products as agreed upon in the Quality Agreement. Societal CDMO shall perform quality inspections and testing of Products before delivery and shall certify test results in the manner agreed upon in the Quality Agreement.

(b) If Societal CDMO fails to meet Client's quality standards for the Products as agreed upon in the Quality Agreement, Societal CDMO shall provide support as requested by Client to address and correct such quality concerns. In addition to its other rights and remedies, Client may hold Societal CDMO responsible for documented costs associated with quality-issue investigation and containment to the extent caused by Societal CDMO's grossly negligent acts or omissions or material breach of this Agreement.

(c) Societal CDMO shall provide Client, as part of release documentation, all Batch related documentation, including but not limited to executed Batch Records, equipment data output, analytical and quality control test results and associated data

3.2. Protection Against Supply Interruptions. In the event that Societal CDMO identifies any foreseeable or anticipated event or circumstance that could interrupt or delay Societal CDMO's performance under this Agreement ("Delay Circumstance"), Societal CDMO shall promptly notify Client of any such Delay Circumstance and use commercially reasonable efforts to minimize such Delay Circumstances.

3.3. Duty to Advise. Societal CDMO shall promptly provide written notice to Client of any of the following events or occurrences, or any facts or circumstances reasonably likely to give rise to any of the following events or occurrences: (a) any failure for any reason by Societal CDMO to perform any of its obligations under this Agreement or any Statement of Work; (b) any delay in delivery of Products; (c) any defects or quality problems relating to Products; (d) any deficiency in the Materials; or (e) any failure by Societal CDMO, or its Subcontractors or common carriers, to comply with applicable Regulatory Standards. In addition, Societal CDMO shall promptly notify Client in writing of any change in Societal CDMO's professional certifications.

3.4. Certain Changes.

(a) Societal CDMO shall promptly make any changes Client directs in a Change Order, which may include changes in the Product Specifications, inspection, testing, quality control, methods of packing and shipping or the date or place of delivery. Any changes pursuant to this Section 3.4(a) will not affect the Price or time for delivery of Products unless (i) within a commercially reasonable timeframe after Client's notice to Societal CDMO of the change, Client receives from Societal CDMO written notice of a claim for adjustment with all sufficient information and documentation regarding Societal CDMO's costs and production timing resulting from such changes to allow Client to perform an audit and verify such claim, and (ii) after auditing and verifying such claim, the results of such audit indicate that, in order to implement such Client-requested changes, Societal CDMO's actual out-of-pocket costs increased by a material amount or that implementing such changes reasonably and appropriately caused a delay in the delivery date of any affected Products. Societal CDMO may increase the prices hereunder in a per-unit amount solely to the extent necessary to compensate Societal CDMO for such commercially reasonable cost increases (but not to allow for any additional margin). Nothing in this Section 3.4(a) including any disagreement with Client as to any adjustment in price or time for performance, will excuse Societal CDMO from proceeding with this Agreement as changed.

(b) Societal CDMO may not make any changes with respect to the Products or scope of this Agreement without Client's advance written approval, which may be given or withheld in Client's in sole discretion.

4. COMPENSATION AND PAYMENT

4.1. Payments.

(a) Generally. Except as otherwise provided in this Section 4.1 or any Statement of Work, as compensation for the Services performed by Societal CDMO, Societal CDMO will invoice Client the fees set forth in the Statement of Work, in accordance with the invoicing schedule set forth in the Statement of Work. Client shall pay Societal CDMO for all undisputed amounts within thirty (30) days after receipt of an invoice.

(b) Advance Payments. Client shall pay Societal CDMO an agreed upon percentage of the total fees set forth in the invoicing schedule of each Statement of Work upon execution of such Statement of Work, if any (the "Advance Payment"). Societal CDMO shall credit the Advance Payment against any subsequent invoices issued for the Services, until the amount of such credit is fully exhausted. Societal CDMO may delay the commencement of the Services until the Advance Payment is paid by Client.

(c) Milestone Payments. As set forth in the Statement of Work, Societal CDMO shall invoice Client the applicable fees set forth in the Statement of Work upon completion of each milestone set out in the Statement of Work. For the avoidance of doubt, each activity that is assigned a specific milestone price in the Statement of Work shall be treated as a separate milestone hereunder.

(d) Budget Assumptions. Client agrees that the fees set out in each Statement of Work are based upon certain assumptions contained therein and the fees may require adjustment if these assumptions are incorrect. Societal CDMO will notify Client upon any such adjustments. The Parties shall in good faith discuss any corresponding fee adjustments and related amendments to be implemented through a Change Order.

(e) Good Faith Dispute. In the event of any good faith dispute with regard to an invoice, Client shall notify Societal CDMO of such dispute within fifteen (15) days of receipt of the invoice, and any undisputed portion of the invoice shall be paid as provided herein. The Parties will work together in good faith to resolve any dispute with respect to an invoice. Any amounts owed to Societal CDMO shall be paid within thirty (30) days of resolution of such dispute.

(f) Late Fee. Client shall pay interest on undisputed past due accounts at a rate that is equal to the lesser of (i) 1.5% per month or (ii) the maximum amount allowable by law.

(g) Suspension of Services. Upon prior written notice to Client, Societal CDMO may suspend all Services under a Statement of Work until all overdue undisputed outstanding invoices under such Statement of Work have been paid in full.

4.2. Pass-Through Costs. Client shall reimburse Societal CDMO for all reasonable, approved Pass-Through Costs at Societal CDMO's cost plus an additional 10% as a handling fee. Societal CDMO shall invoice any such Pass-Through Costs on a monthly basis, which invoices shall also include proper documentation of such expenses in order to receive reimbursement. Client shall pay Societal CDMO for all undisputed amounts within thirty (30) days after receipt of such invoice. Upon prior written notice to Client, Societal CDMO may suspend all Services under a Statement of Work until reimbursement for any undisputed Pass-Through Costs under such Statement of Work that are past due for more than thirty (30) days have been paid in full.

4.3. Taxes and Duties. Client shall be responsible for all taxes imposed on sales of products or Services by operation of law. The consideration payable under any Statement of Work shall be net of any taxes imposed on the amounts payable to Societal CDMO hereunder. Client will bear the cost of all duties, levies, tariffs, and similar charges (and any related interest and penalties) (together "Duties"), however designated, arising from the performance of the Services by Societal CDMO, including without limitation those imposed as a result of the shipping of materials (including API, materials, components, and final products) to, from or between different Societal CDMO site(s) where required by Client. If such Duties are incurred by Societal CDMO, then Societal CDMO will be entitled to invoice Client for such Duties at the time such Duties are incurred.

5. PROPERTY

5.1. Bailment.

(a) All equipment and other tangible property of every description, including supplies, Materials, machinery, equipment, drawings, photographic negatives and positives, artwork, copy layout, electronic data and other items, furnished by Client either directly or indirectly, to Societal CDMO in connection with or related to this Agreement, or for which Societal CDMO has been at least partially reimbursed by Client, but excluding any equipment or other tangible property approved by Client and any general-purpose raw materials, (collectively, "Bailed Property") is and will at all times remain the property of Client and be held by Societal CDMO on a bailment-at-will basis.

(b) Only Client has any right, title or interest in and to Bailed Property, except for Societal CDMO's limited right to use the Bailed Property in the performance of Societal CDMO's obligations under this Agreement. Societal CDMO shall not use the Bailed Property for any other purpose. Societal CDMO shall maintain appropriate inventory and management control systems with respect to Bailed Property and shall not move any Bailed Property from the Manufacturing Facility without the prior written approval by Client. Client may, at any time, for any reason and without payment of any kind, retake possession of any Bailed Property without the necessity of payment or notice to Societal CDMO, or a hearing or a court order, which rights, if any, are waived by Societal CDMO. Upon Client's request, Bailed Property will be released to Client or delivered to Client by Societal CDMO as soon as practicable. Societal CDMO's continued holding of Bailed Property after demand has been made by Client for delivery beyond what is practicable will substantially impair the value thereof, and, accordingly, Client will be entitled to a court order of possession without any need or proving damages or a bond. To the fullest extent permitted by law, Societal CDMO shall not allow any Encumbrance to be imposed on or attach to the Bailed Property through Societal CDMO or as a result of Societal CDMO's action or inaction, and Societal CDMO hereby waives any Encumbrance that it may have or acquire in the Bailed Property.

(c) Societal CDMO acknowledges and agrees that (i) Client is neither the manufacturer of the Bailed Property nor the manufacturer's agent and (ii) CLIENT HAS NOT MADE AND DOES NOT MAKE ANY REPRESENTATION OR WARRANTY WHATSOEVER, EITHER EXPRESS OR IMPLIED, AS TO THE FITNESS, CONDITION, MERCHANTABILITY, DESIGN OR OPERATION OF THE BAILED PROPERTY OR ITS FITNESS FOR ANY PARTICULAR PURPOSE. Notwithstanding the foregoing, if the bailment relationship described in this Section 5.1 is deemed to be a secured financing transaction, Societal CDMO grants to Client a continuing security interest in any rights or interests Societal CDMO may have in the Bailed Property.

5.2. Maintenance; Risk of Loss. Societal CDMO shall bear risk of loss of and damage to Bailed Property. Societal CDMO shall, at its own expense, insure all Bailed Property with a special form property policy, for its replacement value, in accordance with the terms of Section 13.7. As and when it is commercially reasonable to do so, Client shall, at its sole cost and expense, maintain, repair, refurbish and replace Bailed Property. All replacement parts, additions, improvements, and accessories that are paid for by the client will be noted as Client's property upon their incorporation into or attachment to the Bailed Property. All replacements of Bailed Property will also be Client's property. Client shall replace any missing components of or inserts to any Bailed Property.

5.3. Inventory. Client shall provide a written inventory of all Bailed Property that Client provides to Societal CDMO, and Societal CDMO shall set forth the location of all Bailed Property and otherwise maintain such written inventory and provide a copy of this inventory to Client upon request. Societal CDMO shall mark all Bailed Property permanently and conspicuously to identify it as the property of Client and indicate Client's name and address. Societal CDMO shall promptly sign any documents reasonably requested by Client to evidence all of Client's rights to and interests in Bailed Property. Societal CDMO grants to Client a limited and irrevocable power of attorney, coupled with an interest, to execute and record on Societal CDMO's behalf any documents with respect to Bailed Property that Client determines are reasonably necessary to reflect Client's interest in the Bailed Property.

5.4. Societal CDMO's Property. Unless otherwise agreed to by Client in writing, Societal CDMO, at its sole expense, shall furnish, keep in good condition, and replace when necessary all equipment and other items necessary or helpful for the production of the Products (excluding Bailed Property, "Societal CDMO's Property").

6. SUPPLY OF API AND OTHER MATERIALS

6.1. API Supply. Client shall prepay Societal CDMO in advance for all Pass-Through Costs for all API related to each Statement of Work (in such quantities as are approved by Client in writing) in accordance with Section 4.2 of this Agreement. Societal CDMO shall purchase all such API from a supplier mutually agreed to by the Parties.

6.2. Material Supply.

(a) Acquisition of Materials. Unless otherwise agreed to by the Parties, Societal CDMO shall purchase all Materials related to each Statement of Work. Client shall reimburse Societal CDMO for all Pass-Through Costs related to such Materials (in such quantities as are approved by Client in writing) in accordance with Section 4.2 of this Agreement.

(b) Disposal of Materials. For any Materials purchased by Societal CDMO which have expired, or which no longer have any forecasted requirements, Societal CDMO shall contact Client regarding instructions to either dispose of or ship such Materials to Client. If instructions are not received from Client within thirty (30) days of such notice, Societal CDMO reserves the right, at Client's cost, to dispose of the Materials.

6.3. Qualification of Materials and Vendors. Client is responsible for any vendor qualification of Client furnished materials and for providing any required certificates of compliance for such Client furnished materials. If Client requests that Societal CDMO use a specific vendor to purchase Materials and for all vendors selected by Societal CDMO to purchase Materials exclusively for Client, Societal CDMO will be responsible to audit and secure approval of the vendor at Client's expense.

6.4. Testing. Within twenty (20) Business Days of receipt of each shipment of Materials at the Manufacturing Facility, Societal CDMO shall commence: (a) release testing and such other activities as specified in the appropriate quality document; and (b) inspecting each such shipment for obvious defects and for the shipment's conformance with any accompanying documentation. Societal CDMO shall promptly notify Client of any shipment of Materials which does not meet testing specifications, fails to conform to its accompanying documentation, or otherwise carries obvious defects. Client shall pay the full price and costs for any failed Services if a failure results because of defects or other non-conformities in the Materials, that (i) could not have been discovered by Societal CDMO using the agreed testing methods and (ii) are not due to Societal CDMO's gross negligence in handling or storing such Materials.

6.5. Storage of Materials. Societal CDMO shall label and store all Materials, Work-in-Process and Product in its possession from the time of delivery of Materials to Societal CDMO at the Manufacturing Facility in accordance with all Regulatory Standards, and any agreed storage instructions until delivery of the Finished Product(s) to Client. Societal CDMO shall maintain appropriate inventory and management control systems to ensure that all Materials, Works-in-Process and Product are appropriately allocated.

6.6. Capital Expenditures. Unless otherwise agreed in a separate agreement or set forth in a Statement of Work, if any capital equipment expenditures are required to perform the Services ("Client Capital Requirements"), Societal CDMO will notify Client of such Client Capital Requirements in writing before the Parties sign any Statement of Work for which such Client Capital Requirements will be needed. Societal CDMO and Client will enter into a separate agreement or Statement of Work regarding the payment for and ownership of the Client Capital Requirements.

6.7. Acquisition of Approved Drugs. If Societal CDMO is required to buy any marketed drug product to complete the Services, Client acknowledges that the purchases will be made by Societal CDMO on behalf of Client and that Societal CDMO will assume no responsibility or liability whatsoever for the marketed drug product. All marketed drug product purchases will be prepaid by Client and, unless otherwise agreed to between the Parties, Societal CDMO will only place an order for the marketed drug product once an agreed upon prepayment (in the amount of the cost of such marketed drug) has been received.

6.8. Import of API and Materials. If applicable, Societal CDMO and Client will reasonably cooperate to permit the import of Materials into the United States. For import of API, Client or Client's broker shall be designated as the "Importer of Record." Client's obligation shall include obtaining the proper release of API from the local customs and health authorities in the country of importation and obtaining the proper release of API from U.S. Customs and the FDA or the applicable Customs Agency and Regulatory Authority.

6.9. Client Assistance. Client shall provide Societal CDMO, in a timely fashion, with all relevant information as Societal CDMO may reasonably request to perform the Services.

6.10. Quota Restrictions. Notwithstanding anything to the contrary, the Parties acknowledge and agree that Societal CDMO's obligation to procure a given quantity of API, and Client's obligations to purchase and take delivery of a given quantity of Finished Products, in each case is subject to such Party having sufficient DEA quota (where applicable) to support such quantity of API or Finished Product, as applicable (the "Quotas"). Societal CDMO will use commercially reasonable efforts to obtain sufficient Quotas based on the then-current forecast provided by Client for the corresponding supply period.

7. TERM AND TERMINATION

7.1. Term. This Agreement shall commence as of the Effective Date and shall continue in full force and effect until (a) the fifth anniversary of the Effective Date, or (b) such later date as may be required to complete a specific Statement of Work initiated hereunder (the "Initial Term"). Except to the extent terminated sooner as provided in this Article 5, this Agreement shall automatically renew for additional periods of twelve (12) months (a "Renewal Term"), and together with the Initial Term, the "Term") unless either Party notifies the other Party of its intention not to renew at least twelve (12) months (if prior to the successful completion of process validation batches for the first Product) or twenty-four (24) months (after successful completion of process validation batches for the first Product) prior to the expiration date of the Initial Term or any Renewal Term.

7.2. Termination by Either Party. Without prejudicing any other rights or remedies available at law or in equity, either Party may terminate this Agreement, and any Statement of Work upon the occurrence of any of the following events:

(a) if the other Party is in material breach of any part of this Agreement that cannot be cured, or if the breach can be cured, such Party fails to remedy the breach within (thirty) 30 days after receiving written notice of the breach from the other Party or if the non-breaching Party; or

(b) if the other Party (i) becomes insolvent or is generally unable to pay, or fails to pay, its debts as they become due, (ii) files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, (iii) makes or seeks to make a general assignment for the benefit of its creditors, or (iv) applies for or has appointed a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

7.3. Termination by Client. Client shall have the right to terminate this Agreement, or any Statement of Work, at any time with or without cause upon ninety (90) days prior, written notice to Societal CDMO.

7.4. Termination by Societal CDMO.

(a) Societal CDMO shall have the right to terminate a Statement of Work:

(i) If Client requires rescheduling any part of the Services covered by such Statement of Work for more than six (6) months; provided, however, that Societal CDMO shall use commercially reasonably efforts to engage in meaningful discussions with Client in an effort to accommodate any such requests prior to any termination under this subsection;

(ii) if (A) the Services covered by such Statement of Work are not progressing according to the reasonable expectations of Client, and (B) Societal CDMO and Client cannot agree on the appropriate scope changes or additional financial costs associated with such scope changes; provided, that such lack of progress was due to reasons within Client's reasonable control; provided, further, that Societal CDMO shall use commercially reasonable efforts to work with Client for at least ninety (90) days to resolve such lack of progress prior to any termination under this subsection;

(iii) after six (6) months of inactivity on such Statement of Work; provided, that such inactivity was due to reasons within Client's reasonable control and not agreed to by Societal CDMO; provided, further, that Societal CDMO shall use commercially reasonable efforts to engage in meaningful discussions with Client regarding such inactivity prior to any termination under this subsection; or

(iv) if Societal CDMO reasonably determines that it is unable to perform the Services under such Statement of Work in accordance with applicable regulatory requirements (including OSHA, DEA and FDA regulations) and applicable specifications; provided, however, that Societal CDMO shall use commercially reasonable efforts to work with Client for at least ninety (90) days (after Societal CDMO provides Client with notice of such determination) to make the necessary changes to the Services so that Societal CDMO can comply with applicable regulatory requirements prior to any termination under this subsection.

(b) Societal CDMO shall have the right to terminate this Agreement upon six (6) months prior, written notice to Client, if all Statements of Work have been terminated pursuant to Section 7.4(a).

7.5. Effects of Termination. Upon the effective date of any termination or expiration of this Agreement (or termination or expiration of a Statement of Work without termination of the remainder of this Agreement, in which case, the following provisions shall only apply with respect to such Statement of Work):

(a) Societal CDMO shall:

(i) credit any outstanding balances owed to Client including any un-applied Advance Payment against any outstanding invoices;

(ii) promptly terminate all performance under this Agreement and under any outstanding Statement of Work;

(iii) transfer title and deliver to Client all API, Material, work-in progress and Finished Product completed prior to the effectiveness of the notice of termination; and

(iv) return to Client all Bailed Property and any other property furnished by or belonging to Client, or dispose of such Bailed Property or other property in accordance with Client's instructions (provided that Client will reimburse Societal CDMO for the actual, reasonable costs associated with such disposal).

(b) Client shall pay:

(i) any fees and expenses due to Societal CDMO for the Services rendered in accordance with this Agreement up to the date of completion, expiration or termination including for reasonable wind-down activities associated with the Services;

(ii) all actual costs incurred by Societal CDMO to complete activities associated with the completion, expiration or termination and close of the Services rendered up to the date of completion, expiration or termination including, without limitation, disposal fees or delivery fees that may be payable for any Materials owned by Client to be disposed of by Societal CDMO;

(iii) any additional fees and costs incurred by Societal CDMO with Client's prior, written approval relating to the Services that are required to fulfill applicable regulatory and contractual requirements;

(iv) except in the case of termination by Client pursuant to Section 7.2 or any non-renewal of this Agreement after the Initial Term, any reasonable and actual documented expenses to restore the suite at the Manufacturing Facility that is dedicated to the manufacture of Products to the condition of the suite prior to any build-out required pursuant to any Statement of Work; and

(v) any reasonable out of pocket termination expenses resulting from the wind-down of Services from such early termination.

(c) Client will arrange for the pickup from the Societal CDMO site of all Bailed Property (including, but not limited to, API and other Materials) and other property owned by Client within ninety (90) days or as mutually agreed after the earlier of the completion, termination or expiration of this Agreement or any applicable Statement of Work. Societal CDMO will charge Client a storage fee, as described in Section 11.3, for all Client property stored at the applicable Societal CDMO site after the ninetieth (90^{th}) day following the completion, termination or expiration of this Agreement or any applicable Statement of Work.

(d) Each Party shall, except as required by any Governmental Authority:

(i) return to the other Party or destroy all documents and tangible materials (and any copies) containing, reflecting, incorporating or based on the other Party's Confidential Information;

(ii) permanently erase all of the other Party's Confidential Information from its computer systems, except for copies that are maintained as archive copies on its disaster recovery and/or information technology backup systems. Each Party shall destroy any such copies upon the normal expiration of its backup files; and

(iii) upon the other Party's written request, certify in writing to such other Party that it has complied with the requirements of this Section 7.4(d).

8. INTELLECTUAL PROPERTY

8.1. Client shall retain all rights, title and interests in and to Client's Intellectual Property. Societal CDMO may only use Client's Intellectual Property as needed to perform Services under this Agreement.

8.2. Societal CDMO is, and at all times remains, the sole and exclusive owner of Societal CDMO Intellectual Property. Except as otherwise provided in this Section 8.2, no right, license or ownership interest under, in or to Societal CDMO Intellectual Property is granted to Client. To the extent any Societal CDMO Intellectual Property is incorporated in any deliverable or other work product provided under this Agreement, or is used in connection with the Manufacture of the Product, Societal CDMO hereby grants Client a non-exclusive, perpetual, irrevocable, paid-up, royalty-free, transferable, sublicensable, worldwide license under such Societal CDMO Intellectual Property to use, make, have made, sell, offer to sell, import and otherwise fully exploit any Product or any line extension thereof.

8.3. All right, title and interest in and to any Inventions (including, but not limited to, any and all Intellectual Property rights and Trade Secrets therein) conceived, generated, developed, derived, collected or reduced to practice by or on behalf of Societal CDMO, any of its Subcontractors or Affiliates or any of its or their respective personnel in the course of performing services under this Agreement, specifically related to the development, manufacture, testing, storage packaging, use and/or sale of any Product and/or which incorporates or arises from any confidential information provided to Societal CDMO by or on behalf of Client (collectively, "Client Inventions"), shall be the exclusive property of Client. Societal CDMO shall give Client written notice, as promptly as practicable, of all Client Inventions.

8.4. Societal CDMO hereby makes, and agrees to make (and to cause each of its Subcontractors and Affiliates and its and their respective personnel to make), any and all assignments necessary to effect, exclusively and throughout the world, the ownership by Client of Client Inventions under this Article 8.

8.5. License to Client's Intellectual Property. For the term of this Agreement, Client hereby grants to Societal CDMO, a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property that are necessary or useful to perform the Services, for use by Societal CDMO for the sole purpose of performing the Services for Client.

8.6. Societal CDMO shall, and shall cause its Affiliates and Subcontractors and their respective personnel to, fully cooperate with, and sign any documents reasonably requested by Client, to evidence, confirm, record and perfect such assignments and to obtain, maintain, enforce and/or defend any rights assigned.

8.7. No Conflict or Restrictions. Client acknowledges that, except as set forth in Section 2.6, nothing in this Agreement or any Statement of Work will restrict Societal CDMO from using any Societal CDMO Intellectual Property, in the development and manufacture of products for other Societal CDMO clients or for Societal CDMO's own behalf.

9. INDEMNIFICATION; LIMITATIONS OF LIABILITY

9.1. Indemnification by Client. Client will defend and indemnify Societal CDMO, its Affiliates and their respective directors, officers, employees and agents (collectively, the "Societal CDMO Indemnitees") from all Losses relating to or arising from: (i) the distribution of Client's products or the use of Client's products by patients either as part of or outside of the scope of any clinical trials; (ii) any misrepresentation, negligence or willful misconduct by Client or any of its Affiliates and their respective directors, officers, employees and agents (collectively, the "Client Indemnitees"); (iii) any breach by Client of its obligations or warranties under this Agreement; or (iv) any claim of infringement of any Third Party's intellectual property rights in or by Client's products or that is related to Societal CDMO's use of Client's Intellectual Property to perform the Services. This indemnity will not apply to the extent that these Losses are those for which Societal CDMO is obligated to indemnify the Client Indemnitees under Section 9.2.

9.2. Indemnification by Societal CDMO. Societal CDMO will defend and indemnify the Client Indemnitees from all Losses relating to or arising from: (i) any misrepresentation, negligence or willful misconduct by the Societal CDMO Indemnitees; (ii) any failure to Manufacture Products in accordance with cGMP, where applicable; (iii) the breach by Societal CDMO of any of its obligations or warranties under this Agreement; or (iv) any claim of infringement of any Third Party's intellectual property rights in or by Societal CDMO's Intellectual Property that is used to perform the Services.

9.3. Notice of Claims. If a claim occurs under Section 9.1 or 9.2, the indemnified Party will: (a) promptly notify the indemnifying Party of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with the indemnifying Party in the defense of the claim; and (d) permit the indemnifying Party to control the defense and settlement of the claim, all at the indemnifying Party's cost and expense.

9.4. Remedies; Limitation of Liability.

(a) If Societal CDMO fails to perform any part of the Services in accordance with the terms of this Agreement or any applicable Statement of Work, then without limiting any other remedies available to Client, Societal CDMO will, at Client's option, either: (i) repeat that part of the Services at Societal CDMO's costs except that Client will supply the API (except as provided below); or (ii) reimburse Client for the price for that part of the Services, excluding the cost of the API (except as provided below); provided, that Societal CDMO shall supply the API pursuant to (i) and shall reimburse Client for the cost of API pursuant to (ii) if Societal CDMO's failure to perform Services is due to Societal CDMO's gross negligence or willful misconduct.

(b) Client shall retain title and risk of loss to any API; provided, that Societal CDMO shall reimburse Client for the loss of any API resulting from Societal CDMO's gross negligence or willful misconduct; provided that Societal CDMO's obligation to reimburse Client for the cost of such API shall not exceed the greater of (i) [***] percent ([***]%) of the work actually performed by Societal CDMO under the applicable Statement of Work, and (ii) $[***].

(c) EXCEPT FOR OBLIGATIONS TO MAKE PAYMENT OR WITH RESPECT TO LIABILITY FOR INDEMNIFICATION OR INFRINGEMENT OR MISAPPROPRIATION OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS, UNDER NO CIRCUMSTANCES WHATSOEVER WILL EITHER PARTY BE LIABLE TO THE OTHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR (I) ANY (DIRECT OR INDIRECT) DELAY, PENALTY, LOSS OF PROFITS, LOSS OF PRODUCTION, LOSS OF ANTICIPATED SAVINGS, LOSS OF BUSINESS, LOSS OF GOODWILL OR LOSS OF USE OF CLIENT'S PRODUCT, OR COSTS OF ANY SUBSTITUTE SERVICE 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 THESE DAMAGES.

9.5. Product Warranty; No Debarment; Disclaimer.

(a) The Parties recognize that certain Services, as identified in an applicable Statement of Work, are of a developmental or research nature and the resultant products shall not be intended for commercial use. Client acknowledges and agrees that all timelines set for in such Statements of Work are good-faith estimates. Societal CDMO hereby disclaims any warranties that the Services set forth in such Statements of Work will be successfully completed, or successfully completed within the contemplated time period, despite Societal CDMO's commercially reasonable efforts to do so.

(b) Societal CDMO represents, warrants, and covenants that the Finished Products, at the time of delivery to Client: (i) will have been Manufactured in accordance with, and will fully comply with, the applicable Product Specifications, cGMPs, Regulatory Standards and the terms and conditions of this Agreement, the Quality Agreement and the applicable Statement of Work, (ii) will not be adulterated or misbranded, within the meaning of the Act, and (iii) will be free and clear from all Encumbrances.

(c) Societal CDMO represents, warrants, and covenants that neither Societal CDMO nor any person employed or engaged by Societal CDMO in connection with the Services has been debarred under section 306(a) or 306 (b) of the Act (or under any analogous law in any jurisdiction) and no debarred person will in the future be employed or engaged by Societal CDMO in connection with any Services to be performed hereunder.

(d) SOCIETAL CDMO HEREBY EXCLUDES ALL REPRESENTATIONS, WARRANTIES AND CONDITIONS OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, SOCIETAL CDMO MAKES NO EXPRESS OR IMPLIED WARRANTY OR CONDITION: (I) FOR ANY PARTICULAR RESULTS FROM THE PERFORMANCE OF THE SERVICES OR WITH RESPECT TO ANY DATA OR INFORMATION GENERATED THEREFROM, (II) OF FITNESS FOR A PARTICULAR PURPOSE, OR (III) OF MERCHANTABILITY FOR CLIENT'S PRODUCT, AND THESE WARRANTIES AND CONDITIONS ARE EXPRESSLY EXCLUDED.

(e) Client acknowledges that due to the uncertain and unpredictable nature of certain aspects of the Services, Societal CDMO may make commercially reasonable recommendations before or after the start of the Services to ensure that the Product can be manufactured in a safe and effective way in accordance with applicable regulatory requirements (including OSHA and FDA regulations, and the equivalent regulations in the relevant territory) and applicable specifications. The Parties will discuss in good faith any changes or modifications to the Statement of Work for such Services as required to implement such recommendations. If Client opts to proceed against Societal CDMO's commercially reasonable recommendations (including by failing to agree to a related change proposed by Societal CDMO), then Societal CDMO shall have the right to terminate such Statement of Work pursuant to Section 7.4(a)(iv).

10. DELIVERY AND SHIPPING

10.1. Delivery. Shipments (if applicable) of Products and other deliverables will be made EXW (Incoterms 2020) Societal CDMO's Manufacturing Facility unless otherwise agreed. Risk of loss or damage to Products and deliverables will transfer to Client when Products and other deliverables are loaded onto the carrier's vehicle by Societal CDMO for shipment at the EXW point. Products and other deliverables will be packaged for transport in accordance with Client's instructions.

10.2. Shipments. If Client requests Societal CDMO to coordinate collection of Products and other deliverables with shipper, Societal CDMO shall proceed to do so as an agent of Client and at Client's sole risk and expense on the basis that: (i) unless Client specifies in writing a shipper that Societal CDMO is obliged to use, Client is deemed to have approved and accepted any shipper used by Societal CDMO; (ii) any shipment charges will either be paid by Client direct to shipper or by Societal CDMO to shipper on Client's behalf, in which case Client shall reimburse Societal CDMO for the cost of shipment together with a handling fee of [***]%; (iii) Client shall (x) obtain any applicable export license or other official authorization necessary to export Products and other deliverables, (y) be responsible for complying with all applicable export laws and regulations and will pay any applicable export fees or taxes; and (z) be responsible for maintaining adequate insurance (including transit insurance) for Products and deliverables at all times from delivery.

11. STORAGE AFTER PRODUCT RELEASE OR PROJECT COMPLETION

11.1. Storage of Supplied Items. Excluding retained samples or stability samples, and unless otherwise agreed between the Parties, Client shall pay Societal CDMO a $[***] per month (or the equivalent in the relevant jurisdiction) per pallet, one pallet minimum, storage fee if any commercial Batches of Finished Products (collectively, "Supplied Items") are stored at Societal CDMO under room temperature conditions for more than thirty (30) days after their release for shipment by Societal CDMO. This storage fee will increase to $[***] per month (or the equivalent in the relevant jurisdiction) per pallet, one pallet minimum, for Supplied Items that are controlled substances or for Supplied Items stored longer than ninety (90) days after their release for shipment by Societal CDMO. For Supplied Items stored under other than room temperature conditions, the following storage fees will apply beginning thirty (30) days after the Supplied Items have been released for shipment:

(a) $[***] per cubic foot per month or $[***] per cubic foot per month after ninety (90) days (or the equivalent in the relevant jurisdiction) for all Supplied Items stored at the Societal CDMO site under conditions of $2^{o}C - 8^{o}C$;

(b) $[***] per cubic foot per month or $[***] per cubic foot per month after ninety (90) days (or the equivalent in the relevant jurisdiction) for all Supplied Items stored at the Societal CDMO site under frozen conditions; or

(c) If Client requests storage at conditions different than those stated above, then this will be discussed and agreed between the Parties on a separate basis.

11.2. Right to Reject Storage. Societal CDMO reserves the right, upon written notice to Client, to refuse to store any Supplied Items, at its sole discretion, for longer than ninety (90) days after release for shipment, and Client will assume all risk of loss or damage to the Supplied Items stored for more than ninety (90) days after their release for shipment by Societal CDMO and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Societal CDMO to destroy any Supplied Items, Client shall be responsible for the cost of destruction.

11.3. Stability Storage. Societal CDMO shall, at Client's cost, destroy (or, if requested by Client, make available for pick up by Client) all stability samples that remain in stability storage for more than thirty (30) days after the issuance of a report by Societal CDMO for the final time point for that given storage condition (according to the agreed stability protocol), or after cancellation of a given program. Client may request additional storage time for stability samples beyond thirty (30) days. If Societal CDMO agrees to additional storage time, Client will be charged a storage fee of $[***] per liter per month. The cost of this storage will double after ninety (90) days.

12. REGULATORY FILINGS

12.1. Prior to filing with any relevant regulatory authorities any clinical trial or new drug application that references Societal CDMO or services Societal CDMO has performed, Client will give Societal CDMO a copy of the relevant chemical manufacturing and control (CMC) sections of such application. This disclosure will permit Societal CDMO to verify that such application accurately describes the Services that Societal CDMO has performed and the manufacturing and testing processes that Societal CDMO will perform under this Agreement. Societal CDMO requires fourteen (14) days (for a new application) and ten (10) days (for revisions to an existing application) to perform this review but the Parties may agree to a shorter time for the review as needed.

12.2. If Client does not provide Societal CDMO with the documentation requested above within the time stipulated and if Societal CDMO reasonably believes that Societal CDMO's relationship with the regulatory authority may be jeopardized, Societal CDMO may, in its sole discretion, delay or postpone the regulatory authority inspection which is or is equivalent to the FDA's pre-approval inspection until Societal CDMO has reviewed the requested documentation and is satisfied with its contents.

12.3. If in Societal CDMO's sole discretion, Societal CDMO determines that any of the information related to a regulatory filing provided by Client is inaccurate or deficient in any manner whatsoever (the "Deficiencies"), Societal CDMO will notify Client in writing of the Deficiencies. Until the Deficiencies have been resolved or agreement has been reached with Client for resolution, Societal CDMO reserves the right not to participate in the regulatory authority inspection. If this occurs, Societal CDMO's non-participation in the inspection will not be construed as a breach of any of its obligations under this Agreement.

13. MISCELLANEOUS

13.1. Right to Visit, Audit and Inspect. Client, or representatives thereof (subject to such representatives entering into confidentiality agreements reasonable acceptable to Societal CDMO), have the right to audit Societal CDMO's facilities and systems and review documents as they relate to the manufacture, packaging, testing, shipping and storage of Client's products or deliverables at a time, date and duration mutually agreed upon by the Parties. Societal CDMO will permit one standard cGMP compliance audit to be conducted annually for at least two (2) business days with no more than two (2) people, but such period may be extended if reasonably agreed and warranted. In addition, Client may conduct "for cause" audits if either Party received a warning letter or notice of other regulatory actions from any Governmental Authority related to the products or deliverables subject to this Agreement. All visits, inspections and audits shall be conducted in a manner that does not interrupt or impair in any significant manner the manufacturing operations of the Manufacturing Facility. Client agrees to follow all internal Societal CDMO Standard Operating Procedures and safety policies when visiting any Societal CDMO facility.

13.2. Societal CDMO shall immediately notify Client if a Governmental Authority plans to conduct or conducts an inspection at its Manufacturing Facilities that relates to Client's Product. Societal CDMO's obligations to Client with respect to any such inspection shall be set forth in the Quality Agreement.

13.3. Independent Contractor Status. The Parties are independent contractors under this Agreement, and nothing herein shall be construed to create a partnership, joint venture or agency relationship between the Parties. Neither Party shall have the authority to enter into agreements of any kind on behalf of the other Party and shall have no power or authority to bind or obligate the other Party in any manner to any Third Party.

13.4. Assignment. Neither Party may assign this Agreement and the rights and duties hereunder shall without the prior written consent of the other Party (not to be unreasonably withheld); provided that each Party may assign this Agreement to an Affiliate or to a successor to its business by virtue of merger, consolidation reorganization, stock sale or sale of all or substantially all of such Party's assets (or, in the case of Client, in connection with the sale of all or substantially all of its rights related to a Product, or the licensing of rights with respect to a Product). This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their successors and permitted assigns, if any. This Agreement does not create any Third Party beneficiaries.

13.5. Publicity. Neither Party nor any of its Affiliates or representatives shall (orally or in writing) publicly disclose, issue any press release or make any other public statement, or otherwise communicate with the media, concerning the existence of this Agreement or the subject matter hereof, without the prior written approval of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except if and to the extent that such Party is required to make any public disclosure or filing regarding the subject matter of this Agreement: (a) by applicable law: (b) pursuant to any rules or regulations of any securities exchange of which the securities of such Party or any of its Affiliates are listed or traded; or (c) in connection with enforcing its rights under this Agreement.

13.6. Notice. Whenever a Party hereto is required to give any legal notice, demand or request with respect to this Agreement, such communication shall be effective only if it is in writing and delivered by personal service, email transmission (with satisfactory evidence of receipt), courier service (with satisfactory evidence of delivery) or mailed, certified mail, postage prepaid, addressed as follows:

If to Client, to:

Cingulate Therapeutics LLC
1901 W. 47th Place
Kansas City, KS 66205
Attn: General Counsel
Email: [***]

If to Societal CDMO, to:

Societal CDMO, Inc.
1300 Gould Dr.
Gainesville, GA 30504
Attn: Senior Vice President, Operations
Email: [***]

Such communications shall be effective when they are received by the addressee thereof, but if sent by certified mail in the manner set forth above, they shall be effective two (2) business days after being deposited in the mail or if sent by courier or facsimile transmission they shall be effective on the day after delivery. A Party may change its address for such communications by giving notice thereof to the other Party in conformity with this Section 13.5.

13.7. 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 any applicable Statement of Work and the Confidentiality Agreement is incorporated herein by reference. If the Confidentiality Agreement expires or terminates before 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. Notwithstanding anything to the contrary: (a) all of Client's Intellectual Property, as well as all Release Documents, Batch Records, Master Batch Records and all deliverables provided by Societal CDMO to Client under this Agreement will be deemed to be Client's confidential information (and not Societal CDMO's confidential information) for the purposes of such Confidentiality Agreement and (b) nothing in the Confidentiality Agreement will restrict Client from exercising any of its rights under the license granted in Section 8.2.

13.8. Insurance. Each Party will maintain at its sole cost and expense during the term of this Agreement and for three (3) years after termination or expiration of this Agreement, (a) commercial general liability insurance (including product liability) with limits of not less than $[***] million in the aggregate and (b) special form property policy covering Bailed Property for its replacement value. Each Party shall also maintain such other policies of insurance of the types and amounts customarily carried by their respective businesses which is sufficient to cover their respective liability under this Agreement. Each Party will provide evidence of this insurance upon the request of the other Party and shall name the other Party as an additional insured with waiver of subrogation. The insurance certificate shall provide for a minimum of thirty (30) days' written notice to the insured of a cancellation of, or material change in, the insurance. If a Party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such Party, then such Party shall promptly notify the other Party in writing and the Parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances, provided that in no event shall such Party terminate its insurance policies until such amendments to the insurance provision of this Agreement that are mutually agreed upon by the Parties in writing are enacted.

13.9. Force Majeure. 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 labor disturbances, lockouts, quarantines, communicable disease outbreaks, riots, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity.

13.10. Entire Agreement. This Agreement and all of its attachments, together with the Quality Agreement and any Statements of Work incorporated herein, constitute the entire agreement between the Parties with respect to the Services. To the extent any of the provisions of this Agreement conflict with the terms and conditions of the Quality Agreement, the Quality Agreement will control with respect to quality-related matters, and this Agreement will control in all other respects.

13.11. Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the provisions thereof relating to conflicts of laws. The Parties hereby agree to submit to the jurisdiction of the state or federal courts in the State of Delaware solely for purposes of any claim, action, suit or other proceeding enforcing, interpreting or otherwise related to this Agreement.

13.12. Non-Solicitation. During the term of this Agreement, and for one year after its termination, Client and its Affiliates will not, directly or indirectly, solicit, induce, recruit, encourage or otherwise endeavor to cause or attempt to cause any officer, employee, director or consultant of Societal CDMO or any of its Affiliates who became known to Client or its Affiliates in connection with the Services, to terminate or discontinue their employment, contract or other relationship with Societal CDMO or any Societal CDMO Affiliate. Notwithstanding any of the foregoing, the foregoing restrictions shall not restrict Client or any of its Affiliates from soliciting, inducing, recruit, encouraging or otherwise endeavoring to cause or attempt to cause any person to terminate or discontinue their employment, contract or other relationship with Societal CDMO or any Societal CDMO Affiliate, where such activities arise from (i) any advertisement or announcement made at job fairs, in an online job posting or in other media not targeted to such person or (ii) a referral made to Client or any of its Affiliates on the independent recommendation of a third party recruiter.

13.13. Reservation of Rights. The right and remedies set forth in this Agreement are not exclusive but are in addition to any other remedies the Parties may have at law or in equity. After the expiration or termination of this Agreement, the Parties shall retain all claims, causes of action, defenses, and other rights that it may have at law or in equity.

13.14. Headings. The headings of this Agreement are for purposes of reference only and shall not limit or otherwise affect the meaning hereof.

13.15. No Waiver; Modifications. No provision of this Agreement may be waived, amended or otherwise modified, except by a written agreement signed by each Party hereto. The waiver by a Party of the breach of any provision hereof shall not be construed as a waiver of subsequent breaches or as a continuing waiver of such breach.

13.16. Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity and enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any person or entity or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid and unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other persons, entities or circumstances shall not be affected by such invalidity or enforceability, nor shall such invalidity or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction, unless invalidity of a certain provision affects the entire basis of the bargain for a Party.

13.17. Survival. The following provisions shall survive expiration or termination of this Agreement: Articles 5, 7, 8, 9, 11 and 13.

13.18. Counterparts. This Agreement, the Quality Agreement and any Statement of Work may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement will become binding when any one or more counterparts hereof, individually or taken together, bear the signatures of both Parties. For the purposes hereof, an electronic, .pdf or facsimile copy of this Agreement, the Quality Agreement or any Statement of Work, including signed signature pages hereto, shall be deemed an original.

[*Signature page follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the Effective Date by their duly authorized representatives.

Societal CDMO, Inc.		**Cingulate Therapeutics LLC**	
By	*/s/ Scott Rizzo*	By	*/s/ Laurie A. Myers*
Name	Scott Rizzo	Name	Laurie A. Myers
Title	Sr VP, Operations	Title	COO
Date:	October 24, 2022	Date:	October 24, 2022

Exhibit A-1

FORM OF STATEMENT OF WORK

This Statement of Work, dated as of _____, 20__, is subject to that certain Master Services Agreement (the "Agreement") dated as of October 24, 2022, by and between Societal CDMO, Inc. & Affiliates (including IriSys, LLC and Recro Gainesville LLC) ("Societal CDMO") and Cingulate Therapeutics LLC (the "Client"). The terms and conditions of the Agreement are incorporated by reference into this Statement of Work, and Client agrees to be bound by all of the terms and conditions of the Agreement applicable hereto. Capitalized terms used in this Statement of Work and not defined herein shall have the meanings ascribed to such terms in the Agreement.

Services and scope of work to be performed, including required Materials (if any): [SCOPE OF WORK]

Payment Terms:

For the Services described in this Statement of Work, Client shall pay Societal CDMO [DESCRIPTION OF PAYMENT TERMS] (U.S. Dollars).

Term:

Societal CDMO's Services shall commence on [EFFECTIVE DATE OF THE STATEMENT OF WORK] and continue for a period of [INSERT TERM] months, to expire on [EXPIRATION DATE].

Other Terms: [OTHER TERMS]

Societal CDMO, Inc.		**Cingulate Therapeutics LLC**	
By		By	
Name		Name	
Title		Title	
Date:		Date:	

Exhibit 99.1

Cingulate Announces Agreement with Societal CDMO and Provides Clinical Update

New Partnership will Improve and Advance CING Manufacturing Operations

KANSAS CITY, Kan., October 24, 2022 - Cingulate Inc. (NASDAQ: CING), a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, today announced it has executed a Master Services Agreement (MSA) with Societal CDMO, Inc. (NASD: SCTL), a bi-coastal contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development.

With capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms, Societal CDMO will manufacture all clinical, registration, and commercial batches of Cingulate's lead candidate CTx-1301, an investigational medication for the treatment of Attention Deficit / Hyperactivity Disorder (ADHD). Societal CDMO will dedicate a specific manufacturing suite within its Gainesville, GA facility and outfit it with proprietary equipment supplied by Cingulate.

"Choosing the right manufacturing partner is critical to the success of any pharmaceutical company, and we are excited for the opportunity to work with an organization which has the capacity and operational expertise to provide quality manufacturing at each and every scale," said Cingulate Chairman & CEO Shane J. Schaffer. "As Cingulate continues to advance its mission to bring next-generation medications to patients where standard of care treatments fail to achieve optimal outcomes, we believe that Societal CDMO is the right partner at the right time."

"The work that we will conduct under this MSA with Cingulate provides an excellent opportunity for Societal CDMO to showcase our team's extensive expertise in formulating and manufacturing complex therapeutics to assist in the delivery of innovative drugs to the patients that need them. In fact, the innovative nature of Cingulate's PTR technology platform dictates that we install specialty manufacturing equipment provided by Cingulate into a dedicated suite within our facility, demonstrating Societal CDMO's ability to customize solutions for the unique needs of our individual customers," said David Enloe, chief executive officer of Societal CDMO. "We are pleased that Cingulate has trusted Societal CDMO to carry out these essential activities to support CTx-1301 at such a critical juncture on its path through clinical development and toward commercialization."

Clinical Update

Cingulate is preparing to initiate a Phase 3 adult dose-optimization study later this year for its lead candidate, CTx-1301, to assess onset and duration of efficacy and safety in adults with ADHD. The study is expected to commence in December 2022 and will be conducted by ADHD expert and preeminent board-certified psychiatrist Dr. Ann Childress, MD.

“We believe the onset and duration study is a critical trial for physicians, payers, and patients, and we are delighted that Dr. Ann Childress will be leading this investigation,” Schaffer stated. “She has conducted more than 180 clinical studies and has worked on most of the major psychiatric drugs that have been approved over the last 30 years by various major pharmaceutical companies, and we deeply value her expertise.”

In addition, our CTx-1301 Phase 3 fixed-dose pediatric and adolescent safety and efficacy study is now expected to commence in mid-2023 after the final two dosage strengths for this study are completed by Societal CDMO. Assuming we receive positive clincal results from our Phase 3 trials and the food effect study with data expected in December 2022, we plan to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) in the first half of 2024 under the Section 505(b)(2) pathway.

About Attention Deficit/Hyperactivity Disorder (ADHD)

ADHD is a chronic neurobiological and developmental disorder that affects millions of children and often continues into adulthood. The condition is marked by an ongoing pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development.

In the U.S., approximately 6.4 million children and adolescents (11 percent) aged under the age of 18 have been diagnosed with ADHD. Among this group, approximately 80 percent receive treatment, with 65 percent demonstrating clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence is estimated at approximately 11 million patients (4.4 percent), double the size of the child and adolescent segment combined, however, only an estimated 20 percent receive treatment.

Although there is no single medical, physical, or genetic test for ADHD, qualified mental health care professionals and physicians can provide a diagnostic evaluation after gathering information from multiple sources, including: ADHD symptom checklists, standardized behavior rating scales, detailed histories of past and current functioning, and information obtained from family members or significant others who know the person well. Some practitioners will also conduct tests of cognitive ability and academic achievement to rule out a possible learning disability.

About CTx-1301

Cingulate's lead candidate, CTx-1301, utilizes the Company's proprietary PTR™ drug delivery platform to create a breakthrough, multi-core formulation of the API dexmethylphenidate, a compound approved by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD. Dexmethylphenidate is part of the stimulant class of medicines and increases norepinephrine and dopamine activity in the brain to affect attention and behavior.

While stimulants are the gold-standard of ADHD treatment due to their efficacy and safety, the long-standing challenge remains, providing patients entire active-day duration of action. CTx-1301 precisely delivers three releases of medication at the predefined time, ratio, and style of release to optimize patient care in one tablet. The result is a rapid onset and entire active-day efficacy, with the third dose being released around the time when other extended-release stimulant products begin to wear off.

The company is currently preparing for multiple Phase 3 clinical studies of CTx-1301 to support its upcoming New Drug Application (NDA) submission. These studies will be conducted in the U.S. and are instrumental for the filing of the NDA with the FDA.

About Cingulate®

Cingulate Inc. (NASDAQ: CING), is a biopharmaceutical company utilizing its proprietary PTR™ drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of ADHD, Cingulate is identifying and evaluating additional therapeutic areas where PTR™ technology may be employed to develop future product candidates, including to treat anxiety disorders. Cingulate is headquartered in Kansas City. For more information visit **Cingulate.com**.

About Societal CDMO

Societal CDMO (NASDAQ: SCTL) is a bi-coastal contract development and manufacturing organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, Societal CDMO is a leading CDMO providing therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified-release dosage forms, Societal CDMO has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

Societal CDMO: Bringing Science to Society. For more information about Societal CDMO's customer solutions, visit **societalcdmo.com**.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding our current views and assumptions with respect to future events regarding our business, including statements with respect to our plans, assumptions, expectations, beliefs and objectives with respect to product development, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature. These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. Readers are cautioned that any forward-looking information provided by us or on our behalf is not a guarantee of future performance. Actual results may differ materially from those contained in these forward-looking statements as a result of various factors disclosed in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our Annual Report on Form 10-K filed with the SEC on March 28, 2022. All forward-looking statements speak only as of the date on which they are made, and we undertake no duty to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

# # #

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CINGULATE®

Cingulate Therapeutics

Developing next-generation drug candidates where standard-of-care treatments result in suboptimal outcomes

4Q - 2022

CING-US-116-1023

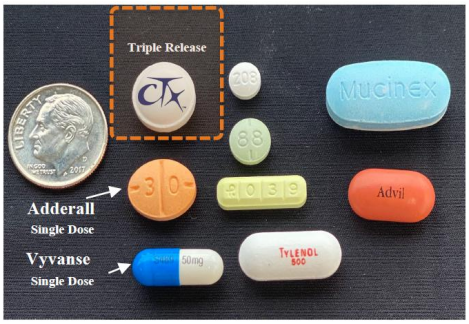
Forward-Looking Statements

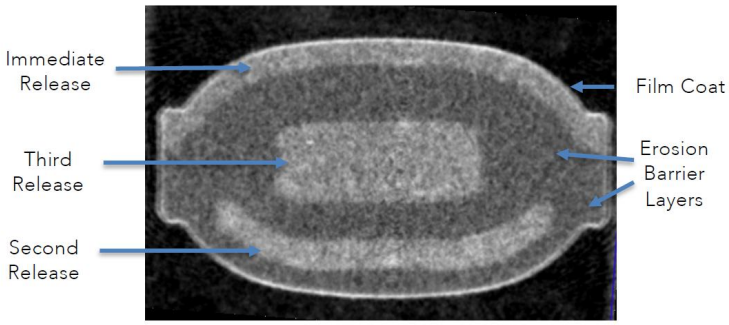
This presentation contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding our current views and assumptions with respect to future events regarding our business, including statements with respect to our plans, assumptions, expectations, beliefs and objectives with respect to product development, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature.

These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. Readers are cautioned that any forward-looking information provided by us or on our behalf is not a guarantee of future performance. Actual results may differ materially from those contained in these forward-looking statements as a result of various factors disclosed in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021. All forward-looking statements speak only as of the date on which they are made, and we undertake no duty to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

Developing Next-Generation Medications in Billion-Dollar Markets

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets





[See the PTR™ Platform in Action]

CINGULATE®

*Symphony Data. 12-months rolling through Jun 2022

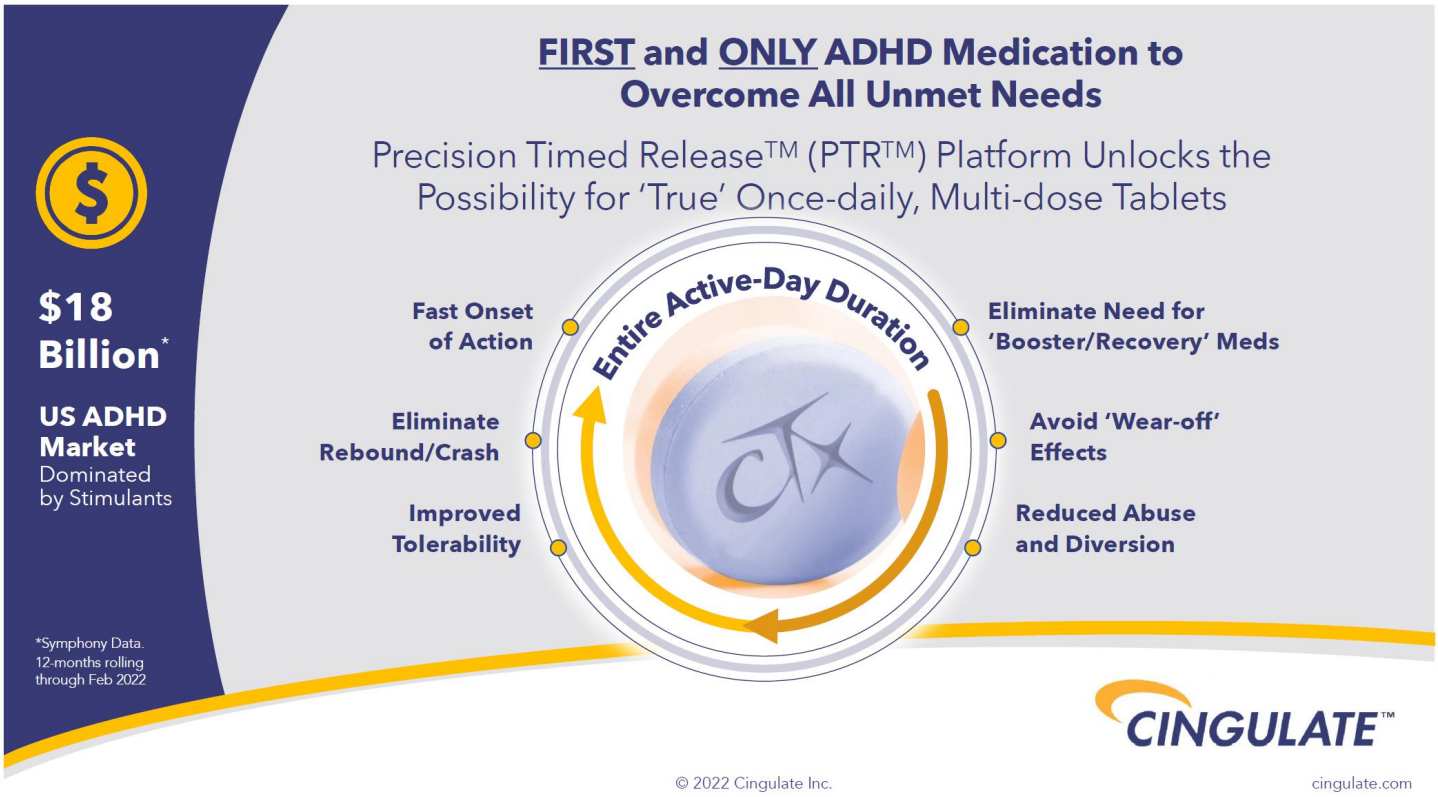
Cingulate.com

Vast Pipeline of Next-Generation Medications Beyond ADHD

- ✓ Leverage PTR platform faster and with less cost in other therapeutics areas
- ✓ Market Criteria:
  - $1Bn+ in peak sales
  - Next-generation mediations with significant improvement over existing therapies

Identified PTR™ Platform Pipeline Opportunities

Near-Term Focus	Future Therapeutic Areas
• CTx-2103 (buspirone) – Anxiety	• Migraine
• Insomnia	• Hypothyroidism
• Depression	• Oral Oncology Medicines
• Bipolar Disorder	• Psychosis
• Parkinson's Disease	• Alzheimer's
• Cardiovascular Disorders	• Pain (Non-Opioid)


FIRST and ONLY ADHD Medication to Overcome All Unmet Needs
Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets
$18 Billion*
US ADHD Market Dominated by Stimulants
*Symphony Data. 12-months rolling through Feb 2022
Entire Active-Day Duration
Fast Onset of Action
Eliminate Need for 'Booster/Recovery' Meds
Eliminate Rebound/Crash
Avoid 'Wear-off' Effects
Improved Tolerability
Reduced Abuse and Diversion
CINGULATE™
© 2022 Cingulate Inc.
cingulate.com

Targeting Treatment of ADHD - $18Bn US Market Opportunity

Frequently diagnosed, chronic pattern interfering with functioning / development

~17 Million US ADHD Patients

Adult ADHD

- ~11M patients in the US and growing (65% of children with ADHD become Adults with ADHD)
- 4.4% of the US adult population
- ~20% receive treatment

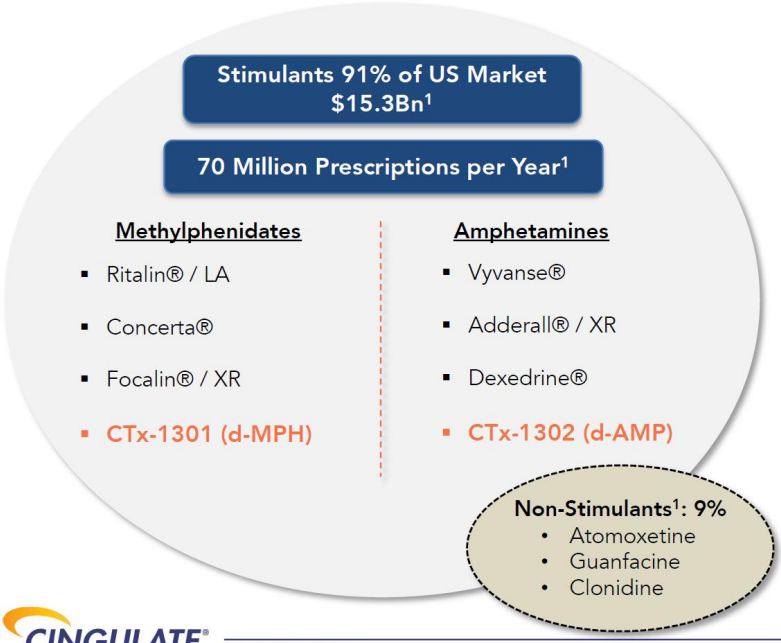
Children & Adolescents

- ~6.4M patients in the US
- 11.0% of the US under 18 population
- ~80% receive treatment

Societal Impact of ADHD
Estimated annual incremental costs of $143 to $266 billion in the United States
Earn ~ 30% less and 10% less likely to be employed
>40% higher rate of car accidents
2x greater divorce rate
2x greater incidence of accidental death
2x higher incarceration rate

References: https://www.cdc.gov/ncbddd/adhd/data.html
Doshi et al. J Am Acad Child Adolesc Psychiatr. 2012;51(10):990-1002.

$18 Billion US ADHD Market Dominated by Stimulants



- ✓ IQVIA Survey of ADHD market found over 60% of providers were currently unsatisfied with available treatment options[3]
- ✓ De-Risked Development
- ✓ 100% of Stimulants Have Been Approved

[1] Symphony Data. 12-months rolling through Jun 2022
[2] Outside the Box: Rethinking ADD/ADHD in Children and Adults A Practical Guide; First Edition, p. 185 Thomas E. Brown, PhD
[3] Unmet Needs in the Treatment of Pediatric and Adult ADHD, J. Rakesh MD et al, Psych Congress, Sept 2017, New Orleans, LA

ADHD Market Currently Dominated by 4 Stimulant Products

Major Unmet Medical Needs Persist

ADHD BRANDS	APPROVED	ATTRIBUTES[1]		UNMET NEEDS[1]			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster[2]
Vyvanse®	2007	2 hours	12 hours	✗	✗	Data Not Available	✗
Adderall® XR	2001	1 ½ hours	10 ½ hours	✗	✗	Data Not Available	✗
Concerta®	2000	2 hours	10 hours	✗	✗	Data Not Available	✗
Focalin® XR	2005	30 mins	11½ hours	✓	✗	Data Not Available	✗

$11.6B
76%
Market
Share ($)[2]

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with 14-16 hours of duration vs. placebo

[1] Information based upon product Package Inserts, and Summary Basis of Approvals for the approved products in chart and Ann C. Childress, Nathalie Beltran, Carl Supnet & Margaret D. Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16.
[2] Symphony Data. 12-months rolling through Jun 2022

ADHD Market Leaders Do Not Provide "Built-In Booster"

Market Leaders Stop Delivery of Medication 4-5 Hours After Administration

ADHD BRANDS	ATTRIBUTES[1]		RELEASE PROFILES[1]		
	Onset	Duration (less onset)	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
Vyvanse®	2 hours	12 hours	100% PRODRUG SUSTAINED RELEASE OVER 2 – 3 HOURS	0	0
Adderall® XR (and generics)	1 ½ hours	10 ½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0
Concerta® (and generics)	2 hours	10 hours	22% IMMEDIATE RELEASE	78% SUSTAINED RELEASE OVER 4-5 HOURS	0
Focalin® XR (and generics)	30 mins	11½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0

[1] Information based upon product Package Inserts, and Summary Basis of Approvals

60%
use short-acting 'booster' dose ***every day!***

CINGULATE®

Source: Outside the Box: Rethinking ADD/ADHD in Children and Adults A Practical Guide; First Edition, p. 185 Thomas E. Brown, PhD

Recent Launches Lack Meaningful Clinical Innovation

Niche Delivery Platforms – Designed to Fail in ADHD

ADHD BRANDS	ATTRIBUTES[1]		UNMET NEEDS			
Product	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy*	Avoid Crash/Rebound	Avoid Booster
Quillivant / Chew® XR	60 mins	8 hours	✗	✗	✗	✗
Mydayis®	2 or 4 hrs	16+ hours	✗	✗	✗	Potentially
Adzenys® ER/ODT	60 mins	8-9 hours	✗	✗	✗	✗
Cotempla® XR/ODT	60 mins	10-12 hours	✗	✗	✗	✗
Aptensio® XR	60 mins	9 hours	✗	✗	✗	✗
Evekeo® / ODT	60 mins	10 hours	✗	✗	✗	✗
Dynavel® XR Oral Susp.	60 min	13 hours	✗	✗	✗	✗
Zenzedi®	60 mins	4-5 hours	✗	✗	✗	✗
Jornay® PM (at night)	2-hour window	10-11 hours	✗	✗	✗	✗
Adhansia® XR	60 mins	12-13 hours	✗	✗	✗	✗
Azstarys® (summer 2021)	Failed Endpoint	Failed Endpoint	✗	✗	✗	✗

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with 14-16 hours of duration vs. placebo

[1] Information based upon product Package Inserts and Summary Basis of Approvals and
Ann C. Childress, Nathalie Beltran, Carl Supnet & Margaret D. Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16.

CINGULATE®

The Cingulate Solution for ADHD Patients & Providers

MASTERY® CTx-1301

ACCOMPLISH® CTx-1302

CING-US-116-1023

Nine Significant Points of Differentiation

NO ADHD product available today combines all unmet needs

- ✓ Provide 'entire active-day' efficacy
- ✓ Fast onset of action
- ✓ Eliminate need for booster/recovery dose
- ✓ Avoid crash and rebound effect

PTR™ technology affords our product candidates the following potential advantages over currently available ADHD treatments

- ✓ Reduce abuse / diversion by eliminating booster
- ✓ Significantly improved tolerability
- ✓ Lower costs to patients, providers, and payers
- ✓ Ability to optimize with 8 dosage strengths
- ✓ Single-enantiomer API selection

CTx-1301 (d-MPH) and CTx-1302 (d-AMP)

Ideal Design Provides Exclusive Ability to Overcome Unmet Needs

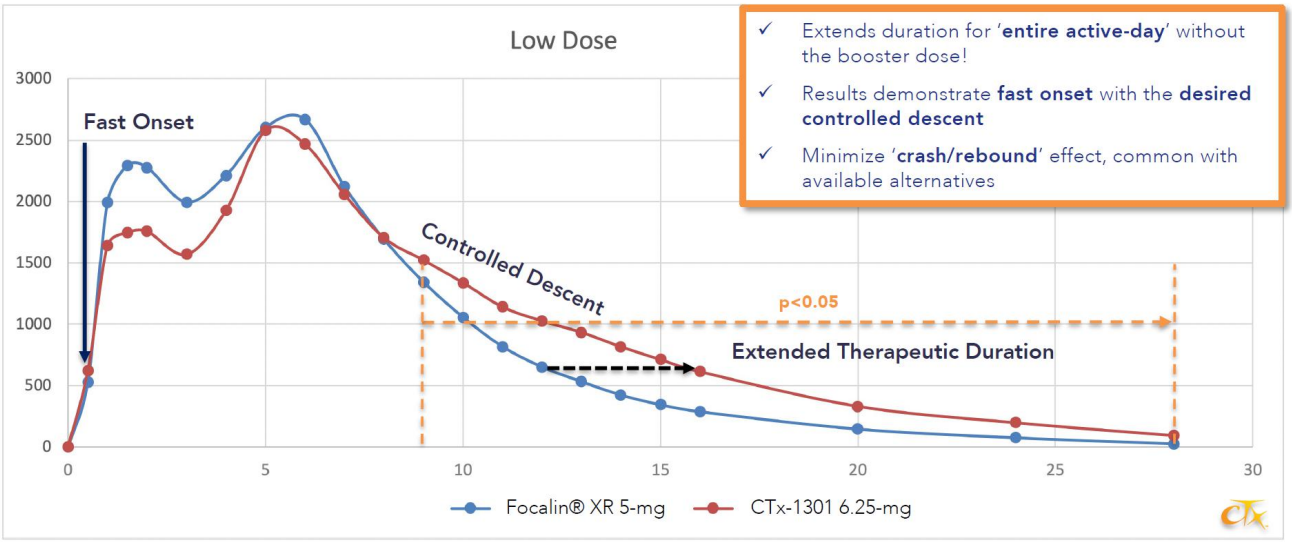
CINGULATE	TARGET ATTRIBUTES		RELEASE PROFILES		
	Onset	Duration	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	35% IMMEDIATE RELEASE	45% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7
CTx-1302 (d-AMP)	30 mins	Up to 16 hours	45% IMMEDIATE RELEASE	35% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7

CINGULATE	TARGET ATTRIBUTES		UNMET NEEDS			
	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy	Avoid Crash/Rebound	Avoid Booster
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	✓	✓	✓	✓
CTx-1301 (d-AMP)	30 mins	Up to 16 hours	✓	✓	✓	✓

6.25-mg 12.5-mg 18.75-mg 25-mg 31.25-mg 37.5-mg 43.75-mg 50-mg

CTx-1301 Clinical Phase 2 Study Results

Plasma dexmethylphenidate (dMPH) Concentration vs Time

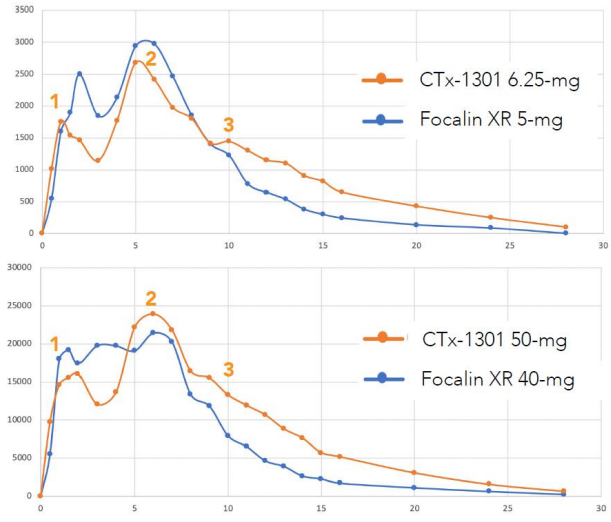


- ✓ Extends duration for '**entire active-day**' without the booster dose!
- ✓ Results demonstrate **fast onset** with the **desired controlled descent**
- ✓ Minimize '**crash/rebound**' effect, common with available alternatives

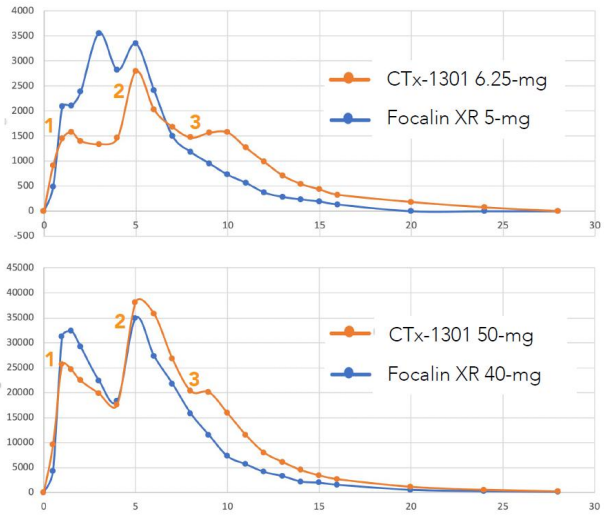
At the Individual Level, Tri-modal Delivery is Clear

Entire Active-Day Efficacy, Stop the Crash & Rebound, Eliminate the Booster Dose

Subject ID: 01-504



Subject ID: 01-510



CTx-1301 Demonstrated Significantly Lower Adverse Events

28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	Focalin XR 5 mg (n=41)	CTx-1301 6.25 mg (n=39)	Focalin XR 40 mg (n=43)	CTx-1301 50 mg (n=42)	All CTx-1301 (n=42)	All Focalin XR (n=44)
Patients with at least one						
Treatment Emergent Adverse Events	7 (17.1%)	4 (10.3%)	22 (51.2%)	14 (33.3%)	17 (40.5%)	25 (56.8%)
Mild	7 (17.1%)	4 (10.3%)	20 (46.5%)	14 (33%)	17 (40.5%)	23 (52.3%)
Moderate	0	0	2 (4.7%)	0	0	2 (4.5%)
Severe	0	0	0	0	0	0
TEAE Related to Study Drug	**5 (12.2%)**	**3 (7.7%)**	**20 (46.5%)**	**13 (31.0%)**	**15 (35.7%)**	**22 (50.0%)**
AE Leading to Study or Drug Withdrawal	1 (2.4%)	0	1 (2.3%)	0	0	2 (4.5%)

There were no serious adverse events.

Source: CSR CTx-1301-001 Listing 16.2.7.1

MASTERY® CTx-1301 Clinical and Regulatory Timeline

CLINICAL

PHASE I
Food Effect Study
n=26

PHASE 3
Adult Dose-Optimization Efficacy and Safety Study to Evaluate Onset and Duration
n~20

Exploratory Endpoints

PHASE 3
Pediatric / Adolescent Fixed-Dose, Placebo-Controlled Study
n=312

PHASE 4
Clinical Program

REGULATORY

NDA Preparation and Filing

NDA Approval ~1H 2025

Target dates; actual timeline may vary

Commercialization to Drive Revenue

Changing dynamics in ADHD commercial landscape

- Ability to dominate share of voice
  - Concerta, Adderall XR, Focalin XR are all off-patent with no promotion
  - Vyvanse loss of exclusivity ~August 2023
- New entrants lack major promotional efforts, field forces, and revenue

Maximize Access for Patients and Providers

- Clinical, Practical, and Societal Story:
  - Efficacy and Tolerability
  - One versus Two Prescriptions
  - Abuse & Diversion
- *Rebates & Net to Plan Cost*
  - PBM's driven by rebate guarantees to payers; estimated >$2B last year*
  - ADHD is a high brand utilization market with high-cost generics at 55-90% of branded drug cost*

Cingulate's Comprehensive Commercial Model

- **Branded product of choice ~ Patients, Providers, & Payers**
- **Strategic partnership to maximize market access, distribution, promotion across all channels**
  - Psychiatry / Neurology & Pediatrics / Family Practice encompass 84% of ADHD market*
  - Maximize and retain NPV to Cingulate

*Symphony Data. 12-months rolling through Jun 2022

Exclusivity: IP, Agreements, and Trade Secrets

Intellectual property rights expected to provide exclusivity through 2035 at a minimum

- OralogiK™ Erosion Barrier Layer
  - Five (5) patents granted (US & Global) expiry dates ranging from 2031 to 2035,
  - One (1) OralogiK™ patent pending (US, Europe)
- Three (3) Cingulate product specific patents under prosecution with USPTO and global entities
  - Pharmacokinetics
  - Trimodal release of API
  - Pharmacodynamics
  - Formulation, Precise Timing, Ratio of API

Exclusivity agreements

- Compression technology exclusivity for branded Cingulate products
- Significant modifications and exclusive process technologies incorporated

Trade Secrets

- Methods, tools, processes, designs, and equipment trade secrets

Cingulate Mission

Develop…

Shape market acceptance, and…

Prepare to commercialize next-generation drug candidates…

Where currently prescribed standard-of-care treatments result in suboptimal outcomes for all stakeholders

Achievement Drives Shareholder and Team Member Value