UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

June 17, 2021

Shane Schaffer
Chief Executive Officer
Cingulate Inc.
1901 W. 47th Place
Kansas City, KS 66205

Re: Cingulate Inc.
Draft Registration Statement on Form S-1
Submitted May 24, 2021
CIK No. 0001862150

Dear Mr. Schaffer:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Cover Page

1. To facilitate an understanding of the transaction, please prominently identify the reorganization and related agreements as an “Up-C” transaction. This should also be stated elsewhere in the prospectus where the transactions are discussed. In addition, please expand your disclosure to explain the material ways in which the structure benefits the company and other related parties. Conflicts of interest related to such benefits should be discussed in the Summary and Risk Factors section.

Basis of Presentation, page ii

2. The pro forma condensed consolidated financial data you refer to appears to relate to the presentation of capitalization and dilution sections of this submission. Please provide a pro forma condensed balance sheet and pro forma condensed statements of comprehensive income for the latest annual and interim periods presented to illustrate how the organizational transactions described on page 69 will impact the historical financial statements. As a smaller reporting company, you may refer to Article 11 of Regulation S-X for guidance.

Prospectus Summary
Overview, page 1

3. Please balance your Summary disclosure by discussing the competitive landscape applicable to your product candidates and the uncertainty surrounding the performance of your product candidates in clinical trials, given the stage of development of each.

4. Please make the following revisions, both in the Summary Overview and throughout the prospectus where similar statements or claims are made:
   - Remove statements that your October 2020 Phase 1/2 trial of CTx-1301 in ADHD patients established "safety" of CTx-1301, as safety and efficacy determinations are the exclusive purview of the the FDA or other regulators;
   - Remove statements that CTx-1301 is a "late-stage asset," as this implies that the product is farther into the development process than it really is;
   - Remove statements that you plan to initiate Phase 3 trials for CTx-1302 in 2022, as this statement presumes that your Phase 1/2a trials will be successful;
   - Remove statement that you plan to submit new drug applications for CTx-1301 and CTx-1302 in the first half of 2023 and in 2024, respectively, as this statement presumes that your Phase 3 trials will be successful.

   Please ensure that similar statements on page 94 are also revised or removed.

Our Clinical Development Pipeline , page 2

5. Please make the following revisions to your pipeline table on pages 2 and 95:
   - Provide two separate columns for Phases 1 and 2;
   - For CTx-1302, only provide the anticipated milestone for the next trial (e.g., a phase 1/2 trial) rather than listing all future phases;
   - Provide a footnote to explain the use of the trademarks "Mastery" and "Accomplish" in the Anticipated Milestones column;
   - Remove the shaded orange arrows so the only progress arrows included accurately depict the progression of development achieved for each product candidate to date. The table should be a reflection of the narrative disclosure in the prospectus and should not be used to prematurely project successful completion of the stages required prior to commercialization.
   - Combine the "PTR Platform Proof of Concept" column and the "Formulation

Development" columns, as both relate to pre-clinical development. Additional columns should not be added to the pipeline table to create the impression of further progress. Note that we will not object to pre-clinical stage columns labeled as "discovery" and/or "IND-enabling."

Our Proprietary Precision Timed Release Drug Delivery Platform Technology, page 3

6. We note your disclosure here and throughout the filing that you believe your timed release drug delivery platform technology will "lower abuse potential" because it will "eliminate[] the need for a second stimulate dose." This statement appears to be incomplete, as you state on page two that "CTx-1301 and CTx-1302 product candidates both contain 3 doses of active pharmaceutical ingredient combined into one small tablet." Please ensure that any statements concerning "lower abuse potential" are properly balanced with disclosure that that one dose of CTx-1301 or CTx-1302 is the equivalent of three doses of other Schedule II stimulants.

Our Strategy, page 4

7. We note your disclosure that you intend to "[r]apidly advance through clinical trials and eventually obtain regulatory approval for CTx-2103 for the treatment of anxiety." Please revise this disclosure to remove any implication that you will be successful in commercializing your product candidates in an accelerated manner, as such statements are speculative and outside of the company's control given the extensive regulatory process and approvals required. Ensure that similar language throughout the prospectus is also removed.

Our Organizational Structure, page 7

8. Please disclose in this summary section that CTx's shares of Class B common stock will allow it to exercise voting power over Cingulate Inc. at a level that is greater than its overall equity ownership of your business. We note disclosure to this effect on page 72.

9. Please enlarge the post-reorganization charts to ensure the font is legible and include estimated ownership percentages for each branch as you have done in the pre-reorganization chart on page 71.

Risk Factors

We are a development stage biopharmaceutical company with a limited operating history., page 14

10. Your disclosure that you are a "development stage" company contradicts your disclosure on page 1 that you are a clinical stage company. Please revise.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval, page 18

11. Please provide expanded risk factor disclosure concerning the clinical trial risks associated with pediatric trials. We note that two of the three segments for which CTx-1301 and CTx-1302 are being developed are for children (ages 6 -12) and adolescents (ages 13-17).

We rely and expect to continue to rely completely on third parties to formulate and manufacture our preclinical, clinical trial..., page 37

12. Your disclosure that you "have no experience in drug formulation or manufacturing" appears to contradict your disclosure on page 4 that your "founders and management team have many years of experience in the biopharmaceutical space" and possess "substantial experience and expertise across the spectrum of drug development and commercialization of pharmaceutical products[.]" This disclosure also appears to contradict your disclosures on page 96 that you want to "[c]apitalize on our existing cGMP Manufacturing Expertise" and that you "have developed a proprietary, reliable, high output, specialized manufacturing equipment train with the potential for real-time testing and release." Please advise and revise.

Industry And Other Data , page 67

13. Your statement that investors are cautioned not to give undue weight to the market and industry data used in the prospectus may imply an inappropriate disclaimer of responsibility with respect to the third party information. Please either delete these statements or specifically state that you are liable for such information.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Liquidity and Capital Resources, page 90

14. Please revise your liquidity disclosures to address the Tax Receivable Agreement, disclosing your estimates of annual payments and how you intend to fund the required payments under the agreement. In this regard, we note your statements that you expect the future payments under the agreement may be substantial. This information should also be disclosed in the Summary and in the Risk Factors.

Business
Our Strategy , page 96

15. Please remove the statement that you "plan to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in late 2022 with results expected in early 2024. Assuming we receive positive clinical results from our Phase 1/2 bioavailability study, our pivotal Phase 3 trials and additional planned supplementary trials, we plan to submit an NDA for CTx-1302 in the second half of 2024 under the Section 505(b)(2) pathway." Given that you will not initiate a Phase1/2 bioavailability study in ADHD patients until 2022, these

statements are premature and speculative. Additionally, remove the statement that your manufacturing "process has been designed and proven with CTx-1301," as efficacy determinations are the exclusive purview of the FDA or other regulators.

Cingulate's Product Candidates versus Major ADHD Competitors (>75% of the ADHD Market), page 100

16. Please remove the chart entitled "Cingulate's Product Candidates versus Major ADHD Competitors (>75% of the ADHD Market)" from the prospectus. It is inappropriate to provide projected approval dates for the company's product candidates, as these determinations are solely within the purview of the FDA and out of the company's control. In addition, because the company has not conducted head to head studies with the competing products listed, nor has either candidate completed clinical trials, it is inappropriate to present the information as if they have been directly compared and studied.

Our CTx-1301 Clinical Development Program, page 104

17. You note that the proposed clinical program for CTx-1301 consists of three Phase 1 clinical pharmacology studies, but you only report the findings from one Phase 1/2 Bioavailability Trial. Please provide more information about all of these trials including their underlying protocols and results. We also note that you disclose on page one that CTx-1301 is being developed for three main patient segments (children ages 6 -12, adolescents ages 13-17, and adults ages 18+), but that this section does not provide any additional information about the trial results for each of these segments. Please revise or explain.

18. We note the following statement on page 104: "There were no unexpected adverse events, serious adverse events, deaths, or other safety signals." The statement as drafted may be construed to mean that SAEs or deaths occurred as a result of the Phase 1/2 study, but were expected. Please revise to clarify and provide detail regarding any material events.

Figure 3: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in individual Adult ADHD subjects under Fasted Conditions. . ., page 107

19. The font in this figure is too small to be legible. Please enlarge. Additionally, please revise this chart to better clarify whether each of your individual conclusions in these four charts (e.g. "eliminate booster dose" or "stop crash & rebound") applies to both the low and high dose trials or only to a specific trial. As written, it appears that only the lower dose trial concluded that it could "eliminate booster dose" and only the high dose trial concluded that it could "stop crash & rebound."

Our CTx-1302 Clinical Development Program, page 109

20. We note your statements on page 107 and 109 that you "plan to initiate Phase 1, 2 and 3

trials in 2022 and to file an NDA in 2024" and "plan to initiate Phase 3 trials in the fourth quarter of 2021 and to file an NDA in the first half of 2023". In addition, you reference your correspondence with the FDA and state that you believe that the proposed clinical programs and trials "will fulfill the clinical developmental program requirements thus allowing us to seek approval for the treatment of ADHD in patients 6 years and older." Please revise these statements, as they are speculative and premature.

Our Planned Phase 3 ACCOMPLISH Trials, page 110

21. Please clarify that you will only undertake these Phase 3 trials for CTx-1302 should the data from the Phase 1 and Phase 2 trials support continued Phase 3 testing.

Intellectual Property, page 112

22. Please revise your intellectual property disclosure to clearly describe on an individual or patent family basis the type of patent protection granted for each technology, the expiration of each patent held, and the jurisdiction of each patent. In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included.

Patent and Know-How License Agreement with BDD Pharma Limited, page 132

23. Please revise your disclosure concerning the BDD license agreement to disclose the expected expiry of the last-to-expire patent licensed under the agreements or the expected last-to-expire payment obligations.

Executive Compensation
Summary Compensation Table, page 139

24. We note the introduction to the Summary Compensation Table states that the table provides compensation information for the fiscal years ended December 31, 2020 and 2019. However, the table only includes information for 2020. Please revise to include 2019 or explain why such information has been omitted.

Certain Relationships and Related Party Transactions, page 148

25. We note your use of the defined term "Redeemed Members" in this section and throughout the filing, and your statement on page 6 that the Redeemed Members are "certain of [the company's] historical members". Please revise, where appropriate, to identify the members by name. In addition, we note your discussion of a $500,000 promissory note issued to a "Member of the Company". Please identify the member by name. See Item 404(a)(1) of Regulation S-K. Finally, please provide your analysis as to why the related party notes have not been filed as exhibits to the registration statement.

Notes to Consolidated Financial Statements
Note 8 - Profits Interest Plan, page F-16

26. You state on page 87 that a future event, such as a public offering, would create a

modification of the PIUs issued under the Cingulate Therapeutics LLC Equity Incentive Plan. Please tell us:

- what modifications the Plan would call for, including any requirement to convert the PIUs into options to purchase shares of Class A common stock, and
- what terms, if any, are required for a public offering in order to require modification of the PIUs.

Exhibits

27. Please file a tax opinion as an exhibit to the filing or provide us with your analysis as to why the tax consequences of the Up-C reorganization transactions are not material to an investor, and therefore no tax opinion is required to be filed. Refer to Item 601(b)(8) of Regulation S-K and Section III.A.2 of Staff Legal Bulletin 19.

General

28. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Gary Newberry at 202-551-3761 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Dillon Hagius at 202-551-7967 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Steven Skolnick