

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

July 28, 2021

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

Re: Cingulate Inc.

Amendment No. 1 to Draft Registration Statement on Form S-1 Submitted July 19, 2021 CIK No. 0001862150

Dear Mr. Schaffer:

We have reviewed your amended 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.

Amendment No. 2 to Draft Registration Statement

## **Prospectus Summary**

Our Clinical Development Pipeline, page 2

1. We note your response to comment 2. As it concerns CTx-1302 in your pipeline table, please remove the Phase 3 initiation as an anticipated milestone. In this regard, we reassert our prior request that you only provide the anticipated milestone for the next trial (e.g., a phase 1/2 trial), rather than listing all future phases. Relatedly, please remove the statement in the amended pipeline table that "Phase 3 Trials to be initiated upon successful outcome of Phase 1/2BA Trial" because it improperly implies that this trial will be successful.

Shane Schaffer Cingulate Inc. July 28, 2021 Page 2

## **Business**

<u>Cingulate's Product Candidates versus Major ADHD Competitors (>75% of the ADHD Market)</u>, page 82

2. We note your response to comment 16 and reissue the comment. Please remove both charts from this page. As neither CTx-1301 nor CTx-1302 have completed clinical trials, the information provided in the first two rows of each table is unsupported and therefore the tabular comparison to competitors' products is inappropriate.

## Our CTx-1301 Clinical Development Program, page 86

3. We note your response to comment 17 and related amendment on page 89 that you "plan to initiate the additional Phase 1 studies concurrently with our Phase 3 Mastery studies." Please clarify whether your Planned Phase 3 Mastery Study will be impacted by the results of these two Phase 1 studies.

<u>Figure 3: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in individual Adult ADHD</u> subjects under Fasted Conditions, page 89

4. We note your response to comment 19 and reissue the comment, as it does not appear that this figure was changed. Please advise or revise.

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