



DIVISION OF
CORPORATION FINANCE

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

July 14, 2024

Josh Mandel-Brehm
Chief Executive Officer
Camp4 Therapeutics Corp
One Kendall Square, Building 1400 West, 3rd Floor
Cambridge, MA 02139

Re: Camp4 Therapeutics Corp
Draft Registration Statement on Form S-1
Submitted June 14, 2024
CIK No. 0001736730

Dear Josh Mandel-Brehm:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted June 14, 2024

Overview, page 1

1. We refer to your July 20, 2022 press release concerning your Series B financing. We note that your press release indicates that your lead product candidate was designed to treat Dravet syndrome and that you expected to commence clinical trials for this program by mid-2023. We also note that your prospectus disclosure does not mention this program or indicate whether it was one of the legacy programs that you out-licensed in July 2023. Given that this program was recently your lead candidate and given that it appears that your RAP platform was used to develop this candidate, please revise the prospectus (e.g., Summary, Risk Factor, MD&A and Business sections) to address your experience with this program.
2. With reference to your risk factor disclosures on pages 15, 21 and 25, please revise the opening paragraph to provide balance and context to the first sentence as well as to the subsequent performance claims concerning your RAP platform in the same paragraph and

on pages 2-3. In particular, it should be clear that you are in the early stages of development, that you do not have clinical data to support your beliefs and that your approach is unproven and may not lead to successful efforts to identify, discover and develop potential product candidates.

3. You state on pages 1, 4, and throughout the Business section that your lead candidate CMP-CPS-001 has the potential to be the "first disease-modifying therapy" to market for the treatment of the most prevalent UCDs. Please provide context and balance to the statement by clarifying that your belief is based on preclinical studies.
4. Please revise to explain briefly the term "upregulate."

Our RAP platform, page 2

5. As safety and efficacy determinations are solely within the authority of the FDA and comparable foreign regulators and are continually assessed through all phases of clinical trials, please remove or revise any statements that state or imply that your product candidates are safe or effective. By way of example only, we note the statements on pages 2 and 107 regarding your proprietary technology enabling you to design RNA Actuators that "optimize for specificity and safety."
6. With reference to your risk factor disclosure on page 27, please revise to disclose that regulatory authorities to date have not approved any ASOs that are directed towards regulatory RNAs and the resulting uncertainty as to the safety profile of your product candidates.

Our Pipeline, page 3

7. You state that you are advancing a pipeline of programs initially focused on metabolic and CNS disorders with validated disease biology, significant unmet needs and large potential market opportunities. In light of your disclosures on page 29 and elsewhere regarding the "small number of patients" who have the rare diseases on which you are initially focused, please clarify what you mean by "large potential market opportunities."

CMP-CPS-001: Potential treatment for urea cycle disorders, page 4

8. You state that you have designed CMP-CPS-001 to overcome the limitations of other programs in development for the treatment of late onset UCDs by "targeting more than 85% of patients with UCD." Please revise to describe the relevant patient subpopulation(s) you are targeting. In this regard, we note your disclosure on page 123 that assuming the successful completion of your ongoing Phase 1 clinical trial in healthy adult volunteers, you anticipate conducting a Phase 2/3 clinical trial to enroll patients, two years of age or older, who have been diagnosed with OTC deficiency. As applicable, please revise, where appropriate, to discuss risks or challenges associated with pediatric trials.
9. With reference to the risk disclosure on page 25, please provide balance to your page 4 discussion of the NHP studies by disclosing that ureagenesis is not an established clinical endpoint, and that this is one reason why these results should not be interpreted as evidence of efficacy.

CMP-FH: Program for the treatment for heterozygous familial hypercholesterolemia, page 5

10. We note your disclosure that you expect to initiate final GLP toxicology studies to enable the filing of a clinical trial application for your CMP-FH program. Please revise to disclose the jurisdiction(s) where you plan to file such application(s) or clarify that such determinations remain pending. Make similar revisions in the sections throughout the prospectus discussing your CMP-SYNGAP program.
11. You disclose that Heterozygous FH is a common genetic disorder affecting over 3 million patients in the United States and Europe, in the aggregate. To the extent that this genetic disorder is materially less prevalent in other large geographic markets that you might target, please briefly discuss.

Risk Factors

We currently depend on third-party suppliers for the manufacture of our product candidates., page 45

12. We note your disclosure that you rely on third-party suppliers for the manufacture of your product candidates, and that "certain" Chinese biotechnology companies and CMOs supply you with product candidate components.
 - Please tell us whether any Chinese companies you do business with have been named as "companies of concern" in the amended version of the U.S. House of Representatives' draft of the BIOSECURE Act approved on May 15, 2024, or are a subsidiary or affiliate of a named company of concern.
 - Revise your disclosure to include an updated discussion of the pending BIOSECURE legislation that would result in trade restrictions, sanctions, or other regulatory requirements by the U.S. government, which could restrict or even prohibit your ability to work with your contractual counterparties.
 - To the extent you are unable to replace any supply or contract manufacturing agreement(s) with any Chinese counterparty, please consider whether you are substantially dependent on such agreement(s) and whether such agreement(s) are required to be filed pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

If we or our licensors are unable to obtain..., page 51

13. Please revise to explain the significance of composition of matter patents. Also, add a Summary risk factor to highlight the risks of not having this type of patent coverage for your product candidates.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Components of our Results of Operations

Revenue, page 94

14. You state that through the year ended December 31, 2023 you have recognized \$17.4 million in research collaboration and license revenue through your collaboration and license agreements. Since you recognized \$350,000 and none in the years ended December 31, 2023 and 2022, respectively, please clarify in this discussion of the collaboration and licensing agreements to which the \$17.4 million revenue was derived and whether the agreement(s) is ongoing.

Business

The role of regRNA in controlling transcription, page 113

15. We note your disclosure that modest increases in protein expression can lead to clinically meaningful therapeutic benefits in many of the more than 1,200 haploinsufficient or recessive partial loss-of-function indications. Please revise to explain your support for this statement and provide disclosure that explains what is depicted in each of the three columns in the graph. Also revise to explain the term "many" in quantitative terms.

Our solution for UCDs: CMP-CPS-001, page 118

16. Please revise to provide descriptive text to explain in greater detail what the table on page 118 shows and how you interpret those results. Also explain the references to analogs and explain why CMP-CPS-001 could not be used in what appear to be *in vitro* studies of healthy human donor cells.
17. Please revise to explain when you commenced work on this program, including when you identified the target gene and generated the ASO candidate.

Our preclinical studies, page 119

18. Please expand your discussion of your preclinical animal studies as follows:
 - Briefly describe the scope and size of the animal studies and the number of tests conducted. Also, with respect to your discussion of the evaluation of CPS1 upregulation in a mouse *Otc* deficiency model on page 119, disclose the three different dose levels.
 - Wherever you disclose you observed study results that were statistically significant, such as the statistically significant decrease in ammonia levels observed in the preclinical evaluation of CMP-CPS-001 in mice with humanized livers, please revise to provide p-values. At first use of the term p-value, please provide a brief explanation regarding how p-values are used to measure statistical significance and the p-value that you have to achieve to conclude a statistically significant result.

Our ongoing Phase 1 clinical trial, page 123

19. Please revise to explain the reason(s) for conducting your clinical trial in Australia as opposed to the United States, particularly in light of the risks discussed on page 64. With reference to the risk factors on pages 19 and 25, please also tell us whether the utilization of the URT test impacted the decision to conduct the trials in Australia.
20. Please revise to discuss here, and as applicable, on page 25, to explain why URT is not an established clinical endpoint even though it has experienced expanded use in clinical studies.
21. With reference to your disclosure on page 122, please revise your disclosure to discuss the use of sodium acetate as a surrogate biomarker. Explain the basis for concluding that sodium acetate is a valid surrogate for ammonia in humans and discuss whether there are risks that sodium acetate could act differently or measure differently than ammonia.

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License and collaboration agreements

Whitehead Institute patent license agreement, page 128

22. Please revise your disclosure regarding the license agreement with the Whitehead Institute to include a discussion of all material payment terms, including quantification of the past patent expenses paid in addition to the upfront fee, and aggregate potential milestone payments segregated by development and commercial milestone payments.
23. You state that your royalty obligations will terminate on a product-by-product and country-by-country basis upon either the last-to-expire valid claim of a Whitehead Institute patent covering the product, which such patent you state is expected to expire in 2043, or "a specified duration after the first commercial sale." Please disclose this specified duration.

Program-related intellectual property, page 131

24. Please disclose the dates when provisional patent applications were filed and/or when the applications expire.

Exhibits

25. With reference to your disclosures on pages 170-171, please file the employment agreements and indemnification agreements with each of your directors and executive officers.

General

26. 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Please contact Gary Newberry at 202-551-3761 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Sprague Hamill at 303-844-1008 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Thomas Danielski