



DIVISION OF
CORPORATION FINANCE

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

February 5, 2021

Bronson Crouch
Chief Executive Officer
Instil Bio, Inc.
3963 Maple Avenue, Suite 350
Dallas, TX 75219

Re: Instil Bio, Inc.
Draft Registration Statement on Form S-1
Submitted January 12, 2021
CIK 0001789769

Dear Mr. Crouch:

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

Our Pipeline, page 1

1. Please revise your pipeline chart to include separate columns for Phase 2 and Phase 3 trials or tell us the basis for your belief that you will be able to conduct Phase 2/3 trials for all your product candidates. Please also shorten the ITIL-168 arrow for melanoma in the pipeline chart to reconcile with your disclosure elsewhere in the prospectus that you have not yet submitted an IND for this product candidate and revise the "Upcoming Milestones" column of your pipeline chart for ITIL-168 to reflect that your next milestone will be the submission of an IND, as discussed on page 5.
2. We note your inclusion of an undisclosed program at the bottom of your pipeline chart. Given the status of development and the limited disclosure on pages 5

and 120 regarding this program, it seems premature to highlight this program prominently in your Summary pipeline table. Accordingly, please revise to remove this program from the Summary table or advise.

Prospectus Summary
Overview, page 1

3. We note your statement that you are a "clinical-stage" biopharmaceutical company. However, your disclosure elsewhere indicates that you have not yet submitted an IND or conducted a clinical trial. Please revise here and throughout your document to remove your claim that you are "clinical-stage."
4. Please revise your disclosure in the first paragraph here and in Business to clarify, if true, that ITIL-168 was not administered in the compassionate use program.
5. We note your disclosures in the Summary and throughout your document claiming that you are "rapidly" advancing your product candidates and that you will be able to "accelerate" the development and regulatory approval of ITL-168. Please remove these statements or revise to provide appropriate context so that these statements do not imply that you will be successful in developing and progressing your product candidates in a rapid or accelerated manner.
6. We note your use of the term "high unmet medical need" here and elsewhere in the document. Such a term might imply that your products are eligible for fast track designation or priority review granted by the FDA for products that treat certain serious unmet medical needs. Please remove your use of this term throughout or otherwise please explain why you believe use of this term is appropriate.

Our Strengths, page 2

7. We note your discussion of the compassionate use program involving the administration of TIL products similar to ITIL-168 for the treatment of refractory melanoma. Please revise your disclosure here and elsewhere in the document where the results of the compassionate use program are described to clarify that the results from this program do not provide a guarantee that ITIL-168 will be deemed to be safe or effective for the treatment of melanoma or additional indications, and that extensive clinical testing and regulatory approval will be required before ITIL-168 can be commonly prescribed for the treatment of melanoma. In your revisions, please disclose how ORR, CR and DCR were measured and the time periods used for the assessments. Please also revise to disclose that 10 of the 21 patients in the program died from complications arising from disease progression, as indicated on page 114. In addition, please revise to avoid characterizing the results of the program as "compelling" or "positive" as this may create an inference that your product is more likely to be found safe and effective, which is a determination solely in the authority of regulatory agencies such as the FDA.

Our Product Candidates, page 4

8. Please explain to us why you are using ITIL-168 for your planned Phase 2 clinical trial, rather than the TIL products that were administered in the compassionate use program. In your explanation, please also tell us why it is appropriate to summarize the results of the compassionate use program in your prospectus given that your disclosure indicates that ITIL-168 was not administered pursuant to this program.
9. We note your statement that you believe that your Phase 2 clinical trial of ITIL-168 in melanoma could support a BLA submission. Please revise to briefly discuss the basis for your belief that you will be able to submit a BLA for ITIL-168 without conducting a Phase 3 clinical trial.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company, page 8

10. 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

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

Common Stock Valuations, page 95

11. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Business

Our Pipeline, page 101

12. We note your statement that CoStAR+ T cells demonstrated markedly increased activity in preclinical studies. Please revise your disclosure to provide the comparison basis for this statement.

Our TIL Manufacturing Process, page 108

13. Please revise this subsection to discuss your reliance on sole source vendors mentioned on page 38. To the extent you are substantially dependent on any agreements with these parties, please identify them, describe the material terms of such agreements and file the agreements as exhibit. If you believe you are not substantially dependent on the agreements, please provide us with an analysis supporting your belief.

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Page 4

14. We note your statement that you are deploying a team to staff regional processing hubs located near major treatment centers. Please revise to disclose how many of these hubs are currently active and whether you own or lease these facilities.

Safety, page 114

15. Please revise your description of the adverse events observed after TIL infusion to disclose how many adverse events were linked to treatment and whether there were any serious adverse events that were linked to treatment.

Intellectual Property, page 122

16. Please revise to include the jurisdictions of your foreign patent applications.

You may contact Julie Sherman at 202-551-3640 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at 202-551-4224 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Madison A. Jones