United States securities and exchange commission logo

October 28, 2020

Laura Shawver
Chief Executive Officer
Silverback Therapeutics, Inc.
500 Fairview Ave N, Suite 600
Seattle, Washington 98109

Re: Silverback Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted October 2, 2020
CIK No. 0001671858

Dear Dr. Shawver:

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, Submitted October 2, 2020

Prospectus Summary, page 1

1. Balance your disclosure in the first sentence on page 1 by clarifying that you have only one product candidate in early clinical stage. In addition, please revise your statement on page 4 that a key element to your business strategy is to [a]dvance SBT6050 through development and seek expedited approval, as well as any similar references, including on page 110, to avoid any implication that you have the ability to accelerate FDA approvals and commercialization of your product. Please also revise to explain the meaning of your statement on page 110 that you are pursuing clinical development strategies that demonstrate proof-of-concept early. We note that it is not clear from your Business discussion how you intend to seek accelerated approval for your product candidates.

2. In the pipeline table on page 2, which also appears on pages 90 and 108, please tell us why you believe you should include two arrows for SBT6050 given that your narrative

description of the Phase 1 trial in the Business section indicates that there is only one
Phase 1 trial, and so the two arrows merely represent different parts of the same trial. We
also note that the combination with PD-1 inhibitor aspect of the SBT6050 program is not
described in the Summary, nor is PD-1 defined in the Summary. Please also tell us why
you believe the TLR8 agonist program and ASGR1-TGF agonist program should be
included in the pipeline table given they are in the early pre-clinical phase, the selected
targets remain undisclosed, and your narrative disclosure only briefly discusses these
programs.

3. You state that SBT6050 is intended to target tumors such as certain breast, gastric and
non-small cell lung cancers, "among others." However, your pipeline table shows that the
targeted indications are breast, gastric, and NSCLC. Please revise your disclosures here,
and elsewhere in your prospectus as appropriate, to clarify the intended target indications
for this product candidate.

4. Please expand your statement on page 3 that Nectin4 has been clinically validated by
Seattle Genetics to explain that another product targeting Nectin4 was approved, and state
the product's intended indication, as you more clearly explain on page 126.

5. We note the following statements that appear on pages 1 and 3 and elsewhere referring to
[s]ingle agent pharmacological activity" in the first dose-escalation cohort of your Phase
1 trial. Please remove these statements from the Summary as your discussions of trials in
the Summary should be limited to endpoints and serious adverse events. In addition, in the
Business section on page 125, please clarify what type of pharmacological activity
consistent with the potential mechanism of action has been observed, and also
disclose how many patients are referenced by the statement, how many doses were
received by those presenting such activity, the dosage amounts received by those patients,
and the meaning of where data are available.

6. Please incorporate the definition of functional cure from page 129 on page 4.

7. Balance your statement in the second bullet on page 4 that you intend to advance
SBT6050 into "earlier lines of therapy" by also disclosing that you do not expect to
initially seek approval of your product candidates as a first line therapy, as you indicate on
page 27, or advise.

Risks Associated with Our Business, page 5

8. Expand on the penultimate bullet to discuss specifics of how the COVID-19 pandemic has
already affected your trials. For example, you state on page 39 that some of your trial sites
have slowed down or stopped further enrollment of new patients and denied access to site
monitors. Please also similarly revise to provide specifics in your disclosures on pages 91-
92.

Implications of Being an Emerging Growth Company and Smaller Reporting Company, page 6

9. 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.

Risk Factors
If we are required by the FDA to obtain approval of a companion diagnostic test, page 25

10. You state that separate FDA approval may be needed for a companion diagnostic test.
Please explain whether there are currently any existing companion diagnostic tests
available to be used in connection with your product candidate, and if there are not, please
revise to clarify that separate approval would be required, or advise. Please also add a
bullet to your summary risks disclosure on page 5 to explain that your product
candidates will need companion diagnostic assays, and if there are currently no such
existing tests, disclose that these diagnostic tests will need to be separately developed and
approved.

Our principal stockholders and management own a significant percentage of our stock. . ., page 65

11. We note your statement that a significant percentage of your voting stock will be owned
by directors, officers and five percent stockholders and their affiliates upon closing of the
offering. Please revise this risk factor to clarify whether the percentage ownership
disclosed assumes the purchase of any shares in the directed share program. In addition,
please add risk factor disclosure where appropriate that several of your directors were
appointed by your significant shareholders, as you discuss on page 166.

Business
Lead Product Candidate SBT6050: TLR8 Agonist Conjugated to a HER2 Antibody, page 111

12. On page 114 you state that HER2 expression is "prevalent in meaningfully large patient
sub-populations in a wide variety of tumor types including breast, gastric, non-small cell
lung, colorectal, bladder, uterine, pancreatic, head and neck, ovarian, esophageal, and
gallbladder cancers, providing the potential to address a large HER2-expressing tumor
agnostic market estimated to be more than 160,000 newly-diagnosed patients annually in
the United States based in part on estimated prevalence rates. Please provide the basis for
this conclusion, including the estimated prevalence percentage rates, and such rates in
breast, gastric and NSCLC patients, as your pipeline table indicates that your SBT6050
product candidate is intended for these indications.

13. In your description of SBT6050-S in vitro studies in mice starting on page 118, please
include the number of mice in the study and explain the meaning of "complete response
rate" and mice being cured on page 121.

14. Although your narrative lead-in to the figure at the bottom of page 119 references
functional results of SBT6050 in human and SBT6050-S in mice, the line graph appears to

show only results for mice. Please revise the graphic to display the human comparison or
advise.

15. Please revise the disclosure to provide the number of subjects for the mouse study results described on pages 120-121, explain whether the studies were powered to show statistical significance, and describe how they relate to the FDA's standards of efficacy. Please also provide similar information for your SBT6290 study discussed on page 128.

16. Please provide further details concerning the primate studies mentioned on page 122, including the number of subjects and duration.

17. In the description of your Phase 1/1b trial for SBT6050 on page 124, please clearly state the total anticipated number of participants for each of Part 1 and Part 3.

18. We note your statements on page 124 that the purpose of parts 2 and 4 of your Phase 1/1b trial is to confirm the safety of the RP2D for SBT6050. Please revise these and any similar statements throughout your prospectus that state or imply that your product candidates are safe or effective as these determinations are solely within the authority of the FDA and comparable regulatory bodies.

19. You mention HER2 IHC 2+ and 3+ overexpression, amplifications, and mutations in the addressable market data on page 125. Please explain the relevance of mutations to your SBT6050 product candidate. We note, for instance, on page 124 you only mention expressions and amplifications in describing the eligible patients for your Phase 1/1b trial.
Please also disclose on page 126 the basis for your belief that SBT6050 may benefit more than 48,000 patients annually, and if used in earlier lines of treatment may benefit more than 160,000 patients annually.

20. Please revise the disclosure to specifically explain the basis for believing that you could have product candidates for these applications shown in the graphic on page 135.
Include descriptions of the pre-clinical trials conducted to date.

SBT6290: TLR8 Agonist Conjugated to a Nectin4 Antibody, page 126

21. On page 127 you state that Nectin4-expressing tumors as shown in the referenced figure represents "over 80,000 patients annually in early line settings and over 16,000 patients with relapsed or refractory cancer annually in the United States. Please revise your narrative disclosure to clarify how the figure on page 127 reflects early line and relapsed or refractory cancer, given the legend states the figure shows incidence of Nectin4 expression and yearly deaths with Nectin4 expression in the United States, and the percentages in the graphic appear to mean that these amounts should be further reduced.

22. Please further explain your lead-in disclosure to the graphics on page 128, including the significance of the vertical axis.

SBT8230: TLR8 Agonist Conjugated to an ASGR1 Antibody, page 129

23. Please label the vertical axis for the graphic at the top of page 131. In addition, revise your lead-in disclosures on page 133 to clarify the significance of the three charts on page 133 and the top chart on page 134, including defining AAV-HBV and

explaining the vertical
axes. Also disclose the number of mice in the studies, and whether the studies were
powered for statistical significance.

Intellectual Property, page 140

24. Please provide the foreign jurisdictions applicable to the patent and patent applications
listed on pages 140-141.

Certain Relationships and Related Party Transactions, page 186

25. On page 189 you state that shares under the directed share program will be offered to
"certain" of your directors and officers. Please clarify if all of your directors and executive
officers are eligible to participate in the program.

Principal Stockholders, page 190

26. We note that the last row of the principal stockholder table on page 191 reflects a total of
3,962,094 for all current executive officers and directors as a group, yet certain executive
officers and directors are shown in the table as individually owning more than 3,962,094
shares. Please reconcile this discrepancy.

27. Please revise the disclosure to identify the natural person or persons who have voting
and/or investment control of the shares held by each of your greater than five percent
stockholders on page 191.

Financial Statements
Notes to Financial Statements
12. Licensing Agreement, page F-25

28. Please revise your disclosure regarding the WuXi license agreement to disclose the
amount of upfront license fees paid. In addition, you state here "In the event the Company
manufactures its commercial supplies of a product produced by the Licensed Cell Line
using a manufacturer other than WuXi Bio or its affiliates, the Company will become
obligated to pay WuXi Bio aggregate milestone payments, upon achievement of certain
sales milestones, of up to the low eight figures." Since an amount that is up to the low
eight figures would be material, please revise to disclose the amount that may be paid.
Please provide corresponding disclosures in the Business section.

You may contact Lisa Vanjoske at 202-551-3614 or Tracey McKoy at 202-551-3772 if
you have questions regarding comments on the financial statements and related matters. Please
contact Margaret Schwartz at 202-551-7153 or Dorrie Yale at 202-551-8776 with any other
questions.

Sincerely,

FirstName LastNameLaura Shawver

Division of Corporation Finance

Comapany NameSilverback Therapeutics, Inc.

Office of Life Sciences

cc: Charles Kim, Esq.