United States securities and exchange commission logo

February 19, 2021

Garo Armen
President and Chairman of the Board of Directors
AgenTus Therapeutics, Inc.
3 Forbes Road
Lexington, MA 02421

Re: AgenTus Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted January 22, 2021
CIK No. 0001840229

Dear Dr. Armen:

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 on January 22, 2021

Prospectus Summary , page 1

1. With reference to your glossary of Industry Terms, please revise the Summary to explain each of the terms at first use in the Summary. Also, revise to explain the terms "off-the-shelf" on page 1 and "unmodified" and "targeted" on page 2.
2. With reference to your disclosures on page 39, please revise to discuss your currents plans for separating your resources and functions from those of Agenus.

Overview , page 2

3. We refer to the bottom three rows of your pipeline table under the heading "Targeted

INTELLIGENT iNKT Cells." We note that your Business section disclosure does not discuss any preclinical work that you have conducted to date relating to any of the candidates. In addition, we note that you do not appear to have identified specific targets or have milestones related to future work. Accordingly, it does not appear appropriate to highlight these programs prominently in your prospectus Summary.

Please revise to
remove these programs from the table.
Strategy , page 2

4. We note your disclosure referencing your plans to "rapidly advance" your lead product
candidate, AGENT-797, through clinical development. With reference to your risk
disclosures on pages 15 and 17-18, please balance the Summary disclosure by
highlighting that it takes many years to develop a new medicine and that no allogeneic
iNKT cell therapy has been approved for commercial use by any regulatory authority.
Potential Advantages of Allogeneic iNKT Cell Therapy Compared to Current CAR-T Cell
Therapy, page 6

5. Please tell us your basis for highlighting a more favorable safety and relapse rate profile
relative to the current standard of care given your disclosure on page 17 that no allogeneic
iNKT cell therapy has been approved for commercial use by any regulatory authority. In
addition, we note that it is not clear (i) that your INTELLIGENT iNKT cells are
comparable to the autologous iNKT cells used in the referenced trials or (ii) what is the
basis for your expectation that your INTELLIGENT iNKT cells will have a higher level
of batch homogeneity and consistency than the autologous iNKT cells used in the clinic to
date. Please note that we have similar concerns regarding you disclosures under the
heading "Key Features of Our INTELLIGENT iNKT Cells." Please revise accordingly.
Key Features of Our INTELLIGENT iNKT Cells, page 7

6. Please discuss briefly here or on page 93 the basis for your statement that "allogeneic
iNKT cells may engraft better than other allogeneic cell types and thus require less
lymphodepletion."
Implications of Being an Emerging Growth Company and Smaller Reporting Company, page 8

7. Please provide us with supplemental 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.
Implications of Being a Controlled Company, page 9

8. We note that you are a "controlled company" as defined under the relevant Nasdaq listing
rules. Please disclose your status as a controlled company in the prospectus cover page.
Also, revise the Summary to indicate the equity stake that your parent entity and affiliates

will hold following the offering.

Use of proceeds , page 10

9. You note that you will use a portion of the proceeds to fund the IND submission and
development of AGENT-797 through completion of our planned Phase 1 clinical trial for
the treatment of patients with multiple myeloma and B cell lymphoma. This appears to
contradict your statement that you will have already commenced your

Phase I clinical trial
in January of 2021, under which the IND should already have been submitted. Please
revise or advise.

Summary Consolidated Financial Data, page 11

10. Please clearly show in the notes how you computed each pro forma amount, including a
discussion of any significant assumptions and estimates used to arrive at the amounts. For
example, please address the following:
Please specifically show in your disclosures how you computed the number of basic
and diluted weighted average shares to use in determining pro forma earnings per
share amounts; and
Your disclosures on page 81 indicate your outstanding convertible note is payable in
cash or equity shares at Agenus election. In this regard, please clarify your basis for
assuming that the notes will be settled in shares of your common stock rather than
cash.
In a similar manner, please expand your disclosures related to the pro forma amounts
presented in the Capitalization table on page 75.

Use of Proceeds, page 73

11. We note your disclosure that you may find it necessary or advisable to use the net
proceeds for other purposes. We also note your risk factor disclosure indicating that you
may experience difficulty in separating your resources from Agenus. Accordingly, please
tell us and, revise as applicable, to discuss whether the proceeds could be used to fund
Agenus operations.

Capitalization, page 75

12. It is not clear why you have not presented any debt amounts in your capitalization table.
Please advise or revise your table accordingly.

13. You disclose that your pro forma amounts reflect the effectiveness of your amended and
restated certificate of incorporation. Please better clarify in your disclosures the specific
terms in the amended and restated certificate of incorporation that you are referring to and
how they will impact your financial statements. It is also not clear whether you intend to
give effect to the conversion of your convertible affiliated note in your pro forma amounts
in a similar manner to the pro forma amounts presented on page 12.

Historical Results of Operations Year Ended December 31, 2019
Research and Development Programs, page 81

14. Please disclose your research and development expenses by product candidate for each
period presented. To the extent that you do not track expenses by product candidate,
please disclose as such, and provide a breakdown by nature of type of expense.

Critical Accounting Policies and Estimates, page 82

15. You disclosures on page F-13 indicate that share-based compensation was issued under
your 2018 Plan as well as under the Agenus 2019 Equity Incentive Plan. Given it would
appear that there would be significant judgment related to share-based compensation,
including how you determined the fair value of your shares in valuing share-based

compensation issued under your 2018 Plan, please include share-based compensation as
part of your critical accounting policies and estimates disclosures and specifically address
the following:
the methods that management used to determine the fair value of your shares and the
nature of the material assumptions involved;
the extent to which the estimates are considered highly complex and subjective; and
the estimates will not be necessary to determine the fair value of new awards once the
underlying shares begin trading.
Alternatively, please advise why you do not think additional disclosures are necessary.

16. Once you have an estimated offering price or range, please explain to us how you determined the fair value of your common stock underlying equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation.

Preclinical Efficacy Data for iNKT Cell Therapy, page 94

17. Please revise to clarify whether this data relates to generic iNKT cell therapies or your INTELLIGENT iNKT cell therapy, AGENT-797. Also, revise to clarify whether you or your patent conducted or sponsored any of these trials. As applicable, please revise your disclosure on pages 96-97 to present the pre-clinical work and results or revise to indicate that such work has not been conducted.

Investigator-Initiated Clinical Data for iNKT Cell Therapy, page 95

18. You state that "[m]ultiple investigator-initiated clinical trials using autologous iNKT cells have demonstrated safety and efficacy across multiple cancer indications, with clinical trials for three different cancers published to date: melanoma, non-small cell lung cancer (NSCLC), and HNSCC." Please remove the implication that autologous iNKT cell have been proven to be safe and effective, as these determinations are the exclusive authority of the FDA or other regulators.

19. Please clarify whether the tables you have included on page 96 refer to the four investigator-initiated clinical trials that you mention in this section. If so, please revise your narrative description to make this more clear, as it appears there are only three clinical trials listed and there is no way to determine which, if any, of the images of the iNKT treatments correspond to each trial.

Additional Product Development
T-Rx, page 98

20. You state that, under your TCR platform, "[s]afety is ensured by using extensive proprietary off-target profiling." Please delete this sentence, as safety determinations are in the purview of the FDA.

Immuno-Oncology Combination Therapy Collaboration with Agenus, page 100

21. It is not clear why you have provided the pipeline table for two of Agenus' products. Please provide an explanation for why the stage of Agenus' clinical development is

material to your investors or remove this pipeline table.
Intellectual Property, page 100

22. You disclose that you own "one issued patent and had 23 pending patent applications." For the issued patent, please amend this disclosure to include the type of patent protection granted (i.e., composition of matter, use, or process), its expiration date, and its the jurisdiction. For the pending patent applications, amend this disclosure to include the date that these patent applications were submitted, their jurisdiction, and their expected expiration date.
Competition , page 112

23. Please revise to clarify whether any of your competitors are testing their therapies on COVID-19-related pneumonia and/or multiple myeloma/B cell lymphoma in clinical trials.

Certain Relationships and Related Party Transactions
Relationship with Agenus, page 129

24. Please disclose the material terms of your Intercompany Agreement with Agenus. For instance, and without limitation, discuss the term and termination provisions and the (i) duration and the applicable markup percentages in your "cost plus basis" agreements. Also, tell us whether the "new services agreement" referenced on page 39 will be executed prior to effectiveness of the registration statement.
Note 2. Summary of Significant Accounting Policies
(h) Revenue Recognition , page F-9

25. You disclose that revenue includes grant income recognized in accordance with ASC 958-605, Not-for-Profit Entities, Revenue Recognition. Please help us understand how you determined it was appropriate to follow the guidance of ASC 985 rather than ASC 606 in regards to revenue recognition. Based on the appropriate guidance, please disclose how you determined the appropriate amount of revenue to record related to the agreement with the Belgium Walloon Region Government as discussed on page F-13. Please also expand your disclosures to discuss the impact of terminating this agreement in 2020.
Financial Statements
Note 10. Related Party Transactions, page F-14

26. Pursuant to SAB Topic 1:B.1, please address the following:
- Please clearly disclose, if true, that the financial statements provided reflect all of the costs of doing business related to these operations, including expenses incurred by other entities on your behalf;
- Please specifically disclose the allocation method used for each material type of cost allocated and your assertion that the methods used are reasonable. Your disclosures indicate that costs were allocated primarily based on time devoted to activities and headcount-based allocations; however, it is not clear what specific allocation method was used for each significant cost; and
- Please disclose management s estimates of what expenses would have been on a stand-alone basis, if practicable.

You may contact Nudrat Salik at (202) 551-3692 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) 551-7976 or Joe McCann at (202) 551-6262 with any other

questions.

Sincerely,

Division of

Office of Life