



DIVISION OF
CORPORATION FINANCE

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

October 18, 2021

Lewis Bender
Chief Executive Officer
Intensity Therapeutics, Inc.
61 Wilton Road, 3rd Floor
Westport, CT 06880

Re: Intensity Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted September 20, 2021
CIK No. 0001567264

Dear Mr. Bender:

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 September 20, 2021

Prospectus Summary

Our Company, page 1

1. We refer to your disclosure that your product candidate INT230-6 utilizes a combination of two proven anticancer cytotoxic agents, cisplatin and vinblastine. Please revise to clarify in the Summary and elsewhere, if true, that both are generic and FDA-approved drugs. Where appropriate, please also provide a brief overview of the FDA approved uses of cisplatin and vinblastine.

2. We refer to your disclosure on page 1 and throughout the prospectus that your lead product candidate INT230-6 has an “excellent safety profile” and has shown “excellent safety” in clinical studies. Please note that determinations of safety and efficacy are solely within the authority of the FDA; therefore, please revise the prospectus to remove all references and/or implications of safety and efficacy, including those cited above.
3. We note your statement on pages 1 and 51 and elsewhere in the prospectus that you seek to develop and commercialize first and best-in-class medicines to treat cancer. The term “first-in-class” and “best-in-class” suggests that your product candidates are effective and likely to be approved as a new class of cancer therapeutics. Given the early stage of development of INT120-6 and your other product candidates, it is not appropriate to suggest that your products are likely to be effective or receive regulatory approval. Please delete these references throughout your registration statement. If your use of the term was intended to convey your belief that the product is based on a novel technology or approach, you may discuss how your technology differs from technology used by competitors.

The report by our auditors includes a paragraph that states that substantial doubt exists about the Company's ability..., page 8

4. Please quantify the total dollar amount to redeem all of the shares of Series A Preferred Stock.

We purchase components for our products from third parties, some of which may be sole source suppliers, page 20

5. We note your disclosure here that in certain cases, the components used to manufacture your product candidates may be sourced from single-source suppliers. Please expand your disclosure to discuss your sources, the availability of raw materials and the names of any principal suppliers. See Item 101(h)(4)(v) of Regulation S-K.

Cautionary Note Regarding Forward-Looking Statements, page 33

6. You state on page 33 that investors are cautioned not to “place undue reliance on” statements that reflect your intentions and expectations disclosed in forward-looking statements. Please note that you are responsible for the disclosure contained in your registration statement and you may not use language that could be interpreted as a disclaimer of information contained in your filing. Please revise.

Use of Proceeds, page 34

7. Please revise to identify the specific product candidates (and target indications, as applicable) for which you intend to use the proceeds of the offering. Please also disclose the approximate amount of proceeds you intend to allocate toward each of the programs identified in the pipeline table and how far the proceeds from the offering will allow you to proceed with the continued development of each of your programs. Refer to Instruction 3 to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 43

8. Regarding your research and development expenses, please disclose the costs incurred during each period presented for each of your key research and development projects. If you do not track your research and development costs by project, please disclose that fact and explain why you do not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that provides more transparency as to the type of research and development expenses incurred (i.e. by nature or type of expense) which should reconcile to total research and development expense on the Statements of Operations.
9. Regarding your general and administrative expenses, separately quantify each item noted for the change from prior periods.

Our Pipeline, page 48

10. Please revise your pipeline table to standardize the width of each of the Phase I, II and III columns. Revise the table to eliminate the separate columns for Preclinical Animal Pharmacology TE and GLP Toxicology, as those stages are not sufficiently distinct. Please also clarify the meaning of the abbreviated target indications included in the first column, such as mTNBC, CRC, SCC, PC, BC and HCC, and delete references to "P3" and "P2/3". Please also discuss, where appropriate, the significance of the different colored circles at the end of the first column of your pipeline table.
11. We refer to your disclosure that that you have designed a Phase 3 study for soft tissue sarcoma, for which you have submitted a protocol synthesis to the FDA, and a Phase 2/3 development plan for the treatment of metastatic triple negative breast cancer (mTNBC). Please clarify whether you have completed Phase 2 studies, as well as the status of the FDA's review and approval of (if applicable) your Phase 3 program for sarcoma and Phase 2/3 program for mTNBC. If the FDA has not approved your planned programs, please shorten the bars under the heading "INT230-6 Sarcomas P3" and "INT230-6 mTNBC P2/3" in your table accordingly.

12. We note the inclusion of your INT33X (Next Generation) discovery program in your pipeline table. Given the status of development and absence of disclosure relating to this program in the Business section, it seems premature to highlight this program prominently in your pipeline table. Please remove this program from the table or advise.

Our Strengths, page 49

13. We refer to your disclosure on page 51 that you have designed and plan to conduct a Phase 3 study of INT230-6 for the treatment of sarcoma based on the data from your metastatic study in sarcoma patients. Please disclose the timeline for the use of INT230-6 for the treatment of sarcoma and your prior discussions with the FDA regarding the review of the trial design for your Phase 1, 2 and 3 programs for the treatment of sarcoma.

INT230-6, Our Lead Product Candidate, page 55

14. We refer to your disclosure of your collaboration with the National Cancer Institute (NCI). Please expand your disclosure to address related statistical significance and/or p-values in your mouse model showing increased absorption with your DfuseRx technology and the growth inhibition experiments. Please also expand your disclosure of your growth inhibition experiments to include the design and scope of your study and to discuss the data from the results to support the conclusions drawn.

Clinical Collaborations, page 58

15. You disclose on page 58 that there were no drug-related serious adverse events in your IT-01 cohort combining INT230-6 and Keytruda. We note your disclosure on page 50 that a few low grade immune-related adverse events were reported in the combination. Please expand your disclosure here to discuss the immune-related adverse events observed, including the number of patients who experienced such symptoms.
16. We note your disclosure on page 59 that Yervoy is a potent drug that has a relatively high percentage of severe side effects. Please expand your disclosure of the severe side effects of Yervoy. You also disclose that the combination of INT230-6 and Yervoy is being evaluated in patients in your Phase 2 cohorts. Please revise to discuss the design and scope of your studies using Yervoy and any immune-related adverse events that have been observed to date. We refer to your disclosure on page 50.
17. We refer to your collaborations with Merck, Bristol-Myers Squibb (BMS) and Ottawa Hospital Research Institute and note that you have entered into clinical trial collaboration and supply agreements with Merck and BMS, both of which will be filed as exhibits to the registration statement. Please confirm if there is a collaboration agreement in place with the Ottawa Hospital Research Institute, and if so, please provide a brief description of the material terms of the arrangement and file the agreement as an exhibit to the registration statement or explain to us why you believe you are not required to do so. Please also revise to include descriptions of the material terms of your collaboration agreements with Merck and BMS. Refer to Item 601(b)(10) of Regulation S-K.

Clinical Trial Results, page 59

18. We note your disclosure on pages 50 and 59 that eight patients experienced grade 3 related adverse events. Please describe the type of grade 3 adverse events observed in your Phase 1/2 study. You also disclose that the most frequent related adverse event included localized tumor related pain. If distinct from the grade 3 adverse events referenced above, please specify the number of patients who experienced localized tumor related pain. Please also include descriptions of the types of grade 1 or 2 adverse events that were observed throughout the prospectus, where applicable.

Data shows that INT230-6 may increase survival in refractory cancer patients, page 60

19. We refer to the results of your metastatic study disclosed on page 61 and study of different markers of cancer proliferation on page 63. Please revise to clarify whether the studies were powered for statistical significance and expand your discussion of the statistical significance and p-values with respect to the survival probability and reduction in the number of tumor cells, respectively (as applicable).
20. We note your discussion of the marked reduction in the amount of live cancer following the first dose of treatment as depicted in the absence of a blue stain in Image B shown on page 63. Please revise the graphic on page 63 to ensure that the significant reduction or absence of blue stain is clearly visible to the lay reader.

Results from Sarcoma Tissue, page 64

21. Please expand your disclosure to specify the primary endpoint of the sarcoma study, whether any adverse events were observed, the number of patients with metastatic soft tissue sarcomas enrolled in the study to date and the number of patients who experienced significant reduction of cancer as shown in Images A and B of the graphic at the bottom of page 64. Please clarify whether there is any overlap between the sarcoma study discussed on page 64 and the 18 sarcoma patients treated in your IT-01 study referenced on page 65.

Competition, page 83

22. We refer to your disclosure on pages 10 and 84 that some of your competitors have developed products and therapies that are similar to your approach of intratumoral delivery or the activation of the immune system, and may also be focused on treating the same disease indications that your product candidates are focused on treating. Please identify any competitors that to your knowledge are using intratumoral technology for the treatment of cancer, including but not limited to, refractory or metastatic cancers.

Intellectual Property, page 84

23. Please revise your disclosure to identify for each issued U.S. patent and patent application the scope of the technology to which each patent or patent application relates, the patent protection and the expiration dates, as applicable.

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Management, page 86

24. For your directors, please disclose the specific skills, qualifications and attributes that led you to the conclusion that the person should serve as your director. Refer to Item 401(e) of Regulation S-K.

Principal Stockholders, page 97

25. Please revise footnote 9 to identify the natural persons who are the beneficial owners of the shares held by Portage Biotech Inc., as well as to list the address of each such natural person.

General

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

You may contact Sasha Parikh at 202-551-3627 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Christopher Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Daniel Woodard, Esq.