United States securities and exchange commission logo

June 3, 2021

Thomas Zindrick, J.D.
President and Chief Executive Officer
Genelux Corporation
3030 Bunker Hill Street, Suite 300
San Diego, CA 92109

Re: Genelux Corporation
Draft Registration Statement on Form S-1
Submitted May 7, 2021
CIK No. 0001231457

Dear Mr. Zindrick:

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 May 7, 2021

Prospectus Summary
Overview, page 1

1. We note your disclosure here and elsewhere implying safety and efficacy of your product candidates, although none of your candidates have received regulatory approval to date. As determinations of safety and efficacy are solely within the authority of the U.S. Food and Drug Administration (FDA) and comparable regulatory bodies, please revise your disclosure throughout the prospectus to remove all claims of safety and efficacy. Note that we will not object to a discussion of objective data resulting from your trials without safety and efficacy conclusions.

2. Please revise the arrows in the pipeline table on pages 2 and 98 to accurately reflect where each product candidate currently stands in development and eliminate any implications of completed phases or steps that have not yet occurred. Please also clarify your rights and responsibilities under the joint venture agreement with respect to your pancreatic cancer program.

3. Please revise your discussion of V2ACT Immunotherapy and the pipeline table on page 2 to clearly disclose that no clinical trial is currently scheduled to be initiated, consistent with your disclosure on page 16. Please also include similar

disclosure in the Business
section.
4. We note your plan to submit an amendment to your IND application in the second
quarter of 2021 and obtain FDA authorization to initiate a registrational Phase 3 trial of
Olvi-Vec in PRROC in the second half of 2021. Please provide balancing disclosure that
you must demonstrate comparability of product manufactured under your updated process
to the product used in the Phase 2 trial, as you state on page 18, disclose why you plan to
submit an amendment to your IND, and clarify whether you have discussed with the FDA
the potential of your Phase 3 clinical trial to serve as a registrational trial.
5. We note that you identify certain entities as investors in your company; however, they do
not appear to be among your principal stockholders as disclosed on page 177. If material,
please expand your disclosure to describe the nature of each named entity's investment in
you and explain to us why including this information is appropriate. Please also explain in
your response your plans to update investors about any changes these entities make with
respect to their investments in the company.

Implications of Being an Emerging Growth Company and Smaller Reporting Company, page 4

6. 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, page 10

7. Please include a risk factor discussing the material risks related to your default on notes
payable and convertible notes payable in the aggregate amount of $1.8 million.

Public health crises such as pandemics, including the COVID-19 pandemic..., page 62

8. We note your disclosure about potential disruptions due to the COVID-19 pandemic. To

the extent you have experienced delays in clinical trials, difficulties enrolling new

participants, participants terminating their participation, or any other disruptions, please
revise the discussion

to describe the events and their potential impact.

Use of Proceeds, page 80

9. Please revise the discussion to separately identify the amounts you intend to allocate to
each of your product candidate's indications and identify the stage of development you
expect to achieve with the proceeds of the offering for each. To the extent you expect to
begin particular stage of development but do not expect to complete it, please indicate that
you will need to raise additional funding to complete that stage of development.
10. We note your plan to pay outstanding accounts payable and accrued liabilities with the

offering proceeds. Please revise here to more specifically discuss any debts you plan to extinguish. Refer to Instruction 4 to Item 504 of Regulation S-K.

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

Critical Accounting Policies and Significant Judgments and Estimates

Stock-Based Compensation, 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. Please discuss with the staff how to submit your response.

Business, page 97

12. We note your disclosure that you formed V2ACT Therapeutics, LLC, a joint venture with TVAX Biomedical Inc., in January 2019. Please expand your disclosure to discuss your accounting policy for the joint venture, and if material, provide the disclosures required by the applicable authoritative accounting guidance.

Business

Overview, page 97

13. Please provide a brief summary of the RECIST rules and criteria referenced throughout the Business section.

Clinical Development of Olvi-Vec, page 104

14. We note your disclosure on page 21 that you previously conducted five Phase 1 clinical studies and one Expanded Access Program in different indications, using different routes of administration, and different dosing regimens. For the clinical trials discussed in this section, please disclose the indication, endpoints, dates of the trials; the number of patients, duration of treatment, dosage information, any serious adverse events that were experienced, including the number of patients experiencing SAEs, and whether the trial achieved its primary endpoint. Please also disclose why you are no longer continuing development in the previous indications.

V2ACT Therapeutics, LLC, page 124

15. Please expand your disclosure to describe the material rights and obligations of each party to the joint venture agreement, including a discussion of how the profits, losses, votes and expenses of the joint venture are allocated between the parties.

Financial Statements

Balance Sheets, page F-3

16. We note that you are in default of convertible notes payable to shareholders in the amount of $1,755 at December 31, 2020. Please expand your disclosure in the section of Liquidity and Capital Resources in your Management's Discussion and Analysis of Financial Condition and Results of Operations to discuss the nature of the loan violations and your remediation plan. Refer to Section 501.03.a of the Financial Reporting Codification for additional guidance.

You may contact Tracie Mariner at 202-551-3744 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Laura Crotty at

202-551-7614 with
any other questions.

Sincerely,

FirstName LastNameThomas Zindrick, J.D.

Division of

Corporation Finance
Comapany NameGenelux Corporation

Office of Life

Sciences
June 3, 2021 Page 4
cc: Amy Hallman Rice, Esq.
FirstName LastName