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June 24, 2021

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attn: Tracie Mariner Vanessa Robertson Jeffrey Gabor Laura Crotty

Re: Genelux Corporation

**Draft Registration Statement on Form S-1** 

Submitted May 7, 2021 CIK No. 0001231457

#### Ladies and Gentlemen:

On behalf of Genelux Corporation (the "Company"), we are responding to the comments (the "Comments") of the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") contained in its letter, dated June 3, 2021, relating to the above referenced confidential draft Registration Statement on Form S-1 (the "DRS"). In response to the Comments, the Company has revised the DRS and is confidentially submitting an amendment to the DRS (the "Amended DRS") with this response letter.

For ease of reference, set forth below are the Company's responses to the Comments. The numbering of the paragraphs below corresponds to the numbering of the Comments, which for your convenience we have incorporated into this response letter. Page references in the text of this response letter correspond to the page numbers of the Amended DRS. Capitalized terms used in this letter but not otherwise defined herein have the meanings set forth in the Amended DRS.

<u>Draft Registration Statement on Form S-1 submitted May 7, 2021</u>

# 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.

**Response:** The Company acknowledges the Staff's Comment and has accordingly updated the disclosure throughout, including on pages 1, 87, and 101 of the Amended DRS.



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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.

**Response:** The Company acknowledges the Staff's Comment and has accordingly revised the pipeline table and added explanatory footnotes on pages 2 and 101 of the Amended DRS, to clarify the stage of development of its product candidates as well as the joint venture arrangement for its 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.

**Response:** The Company acknowledges the Staff's Comment and has accordingly revised and updated the disclosure on pages 2, 101, and 102 of the Amended DRS.

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 a 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.

**Response:** The Company acknowledges the Staff's Comment and has accordingly provided additional disclosure on pages 1 and 101 of the Amended DRS.

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 entity's investment in you and explain to use why including this information is appropriate. Please also explain in your response your plans to update investors about any changes with respect to their investments in the company.

**Response:** In response to the Staff's Comment, the Company has removed the statement identifying certain entities as investors 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.

**Response:** Following the confidential filing of the Amended DRS, the Company will provide to the Staff, on a supplemental basis, copies of the written communications, as defined in Rule 405 under the Securities Act of 1933, as amended (the "*Securities Act*"), that have been used in meetings with potential investors in reliance on Section 5(d) of the Securities Act. Other than the written communications sent to the Walled-Off Investor (as defined below), these materials were only made available for viewing by potential investors during the Company's presentations, and no copies were retained by any potential investor. Pursuant to Rule 418 under the Securities Act, the copies supplementally provided shall not be deemed to be filed with, or a part of, or included in, the Amended DRS.



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To the extent the Company conducts additional meetings, it expects to use the same or similar materials, and the Company undertakes to provide the Staff with copies of any additional written communications that are presented to potential investors in the future by it or anyone authorized to do so on its behalf in reliance on Section 5(d) of the Securities Act, whether or not such potential investors retain copies of such communications.

As discussed telephonically with the Staff, in a single instance, a representative of the Company sent a follow-up email to an investor with whom the Company had held a meeting in reliance on Section 5(d) of the Securities Act (the "Walled-Off Investor"). The Company's email included as attachments written materials describing the Company's clinical development program and results in greater detail. Following consultation with counsel, the Company contacted the Walled-Off Investor and indicated that these materials had been inadvertently provided and requested confirmation that the Walled-Off Investor had not and would not further distribute them to any third parties; the Walled-Off Investor subsequently provided such a confirmation. The Company also confirms that the Walled-Off Investor that received these materials will not be permitted to participate in the offering contemplated by the DRS.

#### 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.

**Response:** The Company acknowledges the Staff's Comment and has included a risk factor related to the notes payable on page 62 of the Amended DRS

## 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.

Response: The Company acknowledges the Staff's Comment and has accordingly enhanced the disclosure on pages 63 and 88 of the Amended DRS

### 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.



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Response: The Company acknowledges the Staff's Comment and has accordingly revised the disclosure on page 81 of the Amended DRS.

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.

Response: The Company acknowledges the Staff's Comment and has accordingly updated the disclosure on page 81 of the Amended DRS to clarify the use of proceeds as it relates to accounts payable. The Company supplementally advises the Staff that it does not currently intend to use the proceeds to repay any outstanding indebtedness as discussed in 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 Strategic Agreements, page 95

Once you have an estimated offering price or range, please explain to us how you determine 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.

Response: The Company acknowledges the Staff's Comment and undertakes that, once an estimated offering price is available, it will provide the Staff with a supplemental letter containing the fair value underlying its equity issuances and an analysis explaining the reasons for any differences between the Company's recent fair value determinations and the estimated offering price.

#### Business, page 97

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.

Response: The Company acknowledges the Staff's Comment and has accordingly expanded the disclosure on pages 88, 89 and F-46 of the Amended DRS.

#### **Business**

Overview, page 97

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

Response: The Company acknowledges the Staff's Comment and has provided the requested summary on page 116 of the Amended DRS.



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## Clinical Development of Olvi-Vec, page 104

14. We note your disclosure of page 21 that you previously conducted five Phase 1 clinical studies and on 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.

Response: The Company acknowledges the Staff's Comment and has accordingly updated the disclosure on pages 109-113 of the Amended DRS.

## 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.

Response: The Company acknowledges the Staff's Comment and has accordingly expanded the disclosure on pages 132 and 133 of the Amended DRS

#### 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.

Response: The Company acknowledges the Staff's Comment and has accordingly updated the disclosure on pages 62 and 96 of the Amended DRS.



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Please contact me at (858) 550-6044 or Amy Hallman Rice at (858) 550-6046 with any questions or further comments regarding the Company's response to the Staff's Comments.

Sincerely,

/s/Jason Kent

Jason Kent Cooley LLP

cc: Thomas Zindrick, Genelux Corporation
Amy Hallman Rice, Cooley LLP
Andrew M. Tucker, Nelson Mullins Riley & Scarborough LLP
Michael K. Bradshaw, Jr., Nelson Mullins Riley & Scarborough LLP

Enclosures