



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

DIVISION OF
CORPORATION FINANCE

December 19, 2019

Brad J. Powers, Esq.
General Counsel
NewLink Genetics Corporation
2503 South Loop Drive
Ames, IA 50010

Re: NewLink Genetics Corporation
Preliminary Proxy Statement on Schedule 14A
Filed November 20, 2019
File No. 001-35342

Dear Mr. Powers:

We have reviewed your filing 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 these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

Preliminary Proxy Statement on Schedule 14A

Summary

The Companies, page 1

1. It appears from your disclosure on page 27 that Lumos has not submitted an investigational new drug application (IND) for its planned Phase 2b trial of LUM-201 for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If true, please revise your summary disclosure to discuss this fact. Please also place your discussion of LUM-201 for the treatment of PGHD in appropriate context with reference to the current clinical development status, including the following, as referenced on pages 25 and 27:
 - Prior clinical trials were conducted by Merck in the 1990s;
 - Two of the Merck trials were discontinued prior to completion due to lack of efficacy;
 - The active pharmaceutical ingredient to be used in the Phase 2b trial was manufactured approximately 15 years prior to the planned start of the trial and may not be approved for use by the U.S. Food and Drug Administration; and

- Not all prior clinical data is available to Lumos for purposes of designing the planned Phase 2b clinical trial.
- 2. We note the disclosure on page 39 that Lumos does not have composition of matter protection in the United States or elsewhere covering LUM-201. If the chemical structure of LUM-201 is in the public domain and Lumos does not own or license, and will not in the future own or license, any composition of matter patents claiming LUM-201, please revise your summary to state that LUM-201 is in the public domain and provide a summary of the potential effects this could have on Lumos' business. Please also include related disclosure, as appropriate, under "Intellectual Property" on page 115.
- 3. Based on your disclosure in the fifth bullet point on page 93, it appears that the merger could be conditioned upon approval of the reverse stock split. Please revise your summary section to clarify if the merger is conditioned upon approval of the reverse stock split proposal.

Background of the Merger, page 59

- 4. Please expand your discussion of the activities that took place during the External Opportunity Review to explain how you narrowed the field of strategic partners from 30 companies to Lumos, Party B and Party C.
- 5. Expand your discussion of the negotiation of the proposed merger to include disclosure of the initial consideration offered, and by which party, and how the parties negotiated and determined the final form and amount of consideration agreed to in the merger agreement, and the amount of the termination fee. Clarify if Stifel made any recommendations regarding those terms.
- 6. We note your disclosure on page 1 that you entered into a license and collaboration agreement with Merck to develop and potentially commercialize your Ebola vaccine V920 product candidate. Please expand your disclosure to discuss how any future royalties you might be entitled to receive factored into your negotiations of the merger consideration offered to Lumos and how the potential for such royalties factored into the board's determination that the merger is in the best interests of NewLink and its stockholders. Please also clarify how the Merck Agreement factored into the analyses performed by Stifel.
- 7. Please update your background discussion for any material developments or activities leading up to Evercel, Inc.'s filing of soliciting materials on December 13, 2019 and update your disclosure for further material developments as appropriate.

Opinion of NewLink's Financial Advisor, page 69

- 8. Please provide us supplementally with copies of all materials prepared by Stifel and shared with the NewLink board, including copies of all board books and all transcripts and summaries, that were material to the board's decision to approve the merger agreement and the transactions contemplated thereby.

Discounted Cash Flow Analysis, page 76

9. In an appropriate place in the proxy statement, please disclose how the perpetuity growth rates used in the calculations presented in this section were determined.

Post-hoc analysis and using a predictive enrichment marker strategy to select appropriate patients, page 110

10. We note your disclosure in last paragraph on page 110 that when only the PEM-Positive children are considered, the growth in response to LUM-201 was enhanced and growth due to rhGH treatment was reduced, when compared to all children, and your disclosure in the paragraph after Figure 5 that in the PEM-Positive children, the growth velocity was not statistically different between rhGH and LUM-201. These conclusions appear to be based on a p-value of 0.082. Given the disclosed p-value, please disclose the basis for your statements. If your disclosed p-value does not meet the FDA's specified threshold for statistical significance for a clinical trial, please revise your disclosure to clarify the p-value that the FDA uses in evaluating the results of a clinical trial and whether the results of the post-hoc analysis would meet such threshold.

Prior clinical experience with LUM-201 in PGHD, page 110

11. We note your disclosure that the first study included a study of biologic response. Please disclose if this study was completed and the results of that study as it related to biologic response.

Expansion of LUM-201 into Additional Endocrine Indications, page 113

12. We note your disclosure on page 104 that you may study the effects of LUM-201 for Turner Syndrome and SGA in a certain subset of patients. Please indicate what portions of the Turner Syndrome and SGA patient populations LUM-201 could address, if approved.

Ammonett and Lumos Merck Agreements, page 115

13. We note your disclosure regarding the Lumos Merck Agreement. Please disclose all material terms of this agreement, including the aggregate amount of each of the development and sales milestone obligations.

Unaudited Pro Forma Condensed Combined Financial Information, page 144

14. We note in the third paragraph that you indicate Lumos was determined to be the accounting acquirer based upon the terms of the Merger Agreement and other factors, including Lumos stockholder's will own approximately 50% of the outstanding common stock of the combined company immediately following the closing of the merger. You also state on page 9 that based on the number of outstanding equity awards and shares of capital stock of each of NewLink and Lumos as of October 15, 2019 holders of NewLink

common stock and equity awards are expected to own approximately 52.8% of the fully-diluted common stock of the combined company. Please provide us with your detailed analysis of how you determined that the transaction qualifies as a reverse merger with Lumos being the accounting acquirer. Refer to the guidance in ASC 805-10-55-10 to 55-15.

15. We also note your disclosure that the Merger is to be accounted for as an asset acquisition rather than a business combination because the assets acquired and liabilities assumed from NewLink do not meet the definition of a business. Please provide us your analysis of how you determined that substantially all the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. Your analysis should also address how the assets and liabilities included in the purchase price allocation on page 150 and in the separate financial statements of NewLink included in the filing represent a single identifiable asset or group of similar assets. Refer to the guidance in ASC 805-10-55-5.

Unaudited Pro Forma Condensed Combined Balance Sheet, page 145

16. We reference the \$36.5 million economic interest in PRV asset included in the purchase price allocation on page 150. Please disclose the nature of this asset and how the fair value was determined. Also, explain to us how you determined the total amount of the purchase price of \$121,448. We note the discussion of the PRV on page 2 that you are entitled to receive a substantial portion of the value of the priority review voucher if it is granted. Explain to us how this was considered in the valuation of the asset.
17. We note that the other intangible assets amount of \$2,978 in the pro forma combined column of the unaudited pro forma condensed balance sheet does not add across. The amount also does not appear to be included in pro forma total assets. Please revise accordingly.
18. Please revise to include an explanation for pro forma adjustment L.

Unaudited Pro Forma Condensed Combined Statement of Operations, page 147

19. Please revise Note I to explain how you determined the pro forma adjustments to basic and diluted weighted shares outstanding.

Principal Stockholders of NewLink, page 155

20. Please identify the natural persons who are the beneficial owners of the shares held by Stine Seed Farm, Inc.

Form of Proxy Card, page II-1

21. Please mark the form of proxy card as "preliminary" pursuant to Exchange Act Rule 14a-6(e)(1).

Brad J. Powers, Esq.
NewLink Genetics Corporation
December 19, 2019
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We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

You may contact David Burton at (202) 551-3626 or Brian Cascio at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Tim Buchmiller at (202) 551-3635 or Christine Westbrook at (202) 551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: James C.T. Linfield, Esq.