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

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934

Filed by the Registrant ☒ Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

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NewLink Genetics Corporation
(Name of registrant as specified in its charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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This Schedule 14A filing consists of the following communication relating to the proposed merger among NewLink Genetics Corporation ("**NewLink**" or the "**Company**"), Cyclone Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company (the "**Merger Sub**"), and Lumos Pharma, Inc., a privately-held Delaware corporation ("**Lumos**"), pursuant to the terms of an Agreement and Plan of Merger and Reorganization dated September 30, 2019 (the "**Merger Agreement**"), by and among NewLink, Merger Sub and Lumos:

Transcript of NewLink's investor call, first used or made available on October 1, 2019.

NewLink Genetics & Lumos Pharma Merger Conference Call

Corporate Participants:

Richard Hawkins, Chief Executive Officer, Lumos Pharma
Carl Langren, Chief Financial Officer, NewLink Genetics
John McKew, PhD, Chief Scientific Officer, Lumos Pharma
Eugene Kennedy, MD, Chief Medical Officer, NewLink Genetics
Lisa Miller, Director of Investor Relations, NewLink Genetics

Operator

Good morning, ladies and gentlemen, and welcome to the NewLink Genetics and Lumos Pharma Merger conference call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session, and instructions will follow at that time.

As a reminder, this conference call is being recorded. I will now turn the call over to Lisa Miller, Director of Investor Relations at NewLink Genetics.

Lisa Miller

Thank you. I would like to remind everyone that certain statements made during this call are forward-looking statements under U.S. federal securities laws. These statements are subject to risks and uncertainties that could cause actual results to differ materially from historical experience or present expectations. Additional information concerning factors that could cause actual results to differ is contained in our periodic reports filed with the SEC. The forward-looking statements made during this call speak only as of the date hereof, and the company undertakes no obligation to update or revise the forward-looking statements. Information presented on this call is contained in the press release we issued yesterday afternoon, and in our Form 8-K also filed yesterday, both of which may be accessed from the Investors page of NewLink's website.

Please note that today's presentation is not an offering of securities or a solicitation of a proxy to vote any securities. The information discussed today is qualified in its entirety by the Current Report Form 8-K that has been filed today by NewLink and may be accessed on the SEC's website, including the exhibits thereto. Investors are urged to read both Form 8-Ks carefully because they contain information about the proposed transaction.

I will now turn the call over to NewLink's Chief Financial Officer, Carl Langren. Carl?

Carl Langren

Thank you, Lisa.

Hello everyone, and thank you for joining us this morning to discuss NewLink Genetics' proposed merger. Yesterday after the market close, NewLink issued a press release announcing our planned merger with Lumos Pharma, a privately held biopharmaceutical company based in Austin, Texas, whose mission, much like our own, is to bring novel therapies to patients with important unmet needs, specifically those who have rare diseases. Together, we believe this shared vision will help us forge a new path forward as we plan to advance our new lead clinical candidate, LUM-201. We are really excited about the prospects for LUM-201, as we believe it represents the first oral secretagogue product candidate for the treatment of pediatric growth hormone deficiency, also known as PGHD, which Rick and the team will talk about shortly. Following the completion of our merger, we will strategically look to augment our pipeline through the acquisition of assets that align with our mission, in addition to potential market expansion for LUM-201 into other rare endocrine disorders where there are established markets and an opportunity to displace existing therapies which are delivered by injections of recombinant growth hormone.

I am pleased to be joined by Rick Hawkins, the CEO of Lumos Pharma, as well as Drs. Gene Kennedy and John McKew whom you will hear from shortly.

I will start today's call by going through an overview of key merger terms and then provide some insight to the rationale and synergies that led both our companies to agree that a merger of equals would support the shared mission of our companies. I will then turn the call over to Rick to discuss Lumos Pharma's core asset and the combined company's strategy.

Our proposed merger structure is that of equals whereby Lumos stockholders will own approximately 50% of the combined company. Rick will become the CEO and work out of our Austin office. In addition, there will be a newly formed board of directors consisting of seven members: three from NewLink, three from Lumos, and one jointly selected. We commenced a restructuring today to better align with our priorities and estimate this will result in substantial cost savings moving forward. Under the restructuring plan, we will reduce our workforce by 28 employees (approximately 60%). This restructuring combined with the departure of Dr. Vahanian, announced yesterday, is expected to decrease our cash payroll expense by approximately $5.0-$6.0 million annually.

Excluding restructuring charges and severance costs relating to departed executives and other employees, we project that the combined company will spend an average of $6.5-$7.5 million per quarter in 2020, down from NewLink's current guidance of cash use of approximately $10 million per quarter as a stand-alone company. We estimate that the December 31, 2019 combined company's unaudited pro forma cash on hand, excluding restructuring charges and severance costs, will be approximately $80 million. We expect this will allow us to reach the Phase 2b readout for LUM-201, a trial which we expect to initiate in the middle of next year. In connection with this transaction, the combined company also plans to implement a reverse stock split.

I will briefly mention that NewLink has an existing license with Merck for our Ebola vaccine. As you may know, Merck initiated submission of a rolling BLA for this vaccine in November of last year. On September 17, 2019, it was announced that the FDA has accepted the biologics license application (BLA) for Ebola vaccine V920 and the Prescription Drug User Fee Act (PDUFA), or target action date, is set for March 14, 2020. If the vaccine receives approval, a priority review voucher would be issued, in which we own a substantial interest and which we plan to monetize. This voucher, in combination with our current cash on hand, would allow us both the flexibility and the resources to seek out potential product candidate acquisitions aligned with our focus on rare diseases. This focus on additional product candidate acquisitions will be an integral piece of our growth strategy and value creation as a combined company. I'll now turn the call over to Rick to formally introduce you to Lumos Pharma, LUM-201, and the exciting vision he shares for our combined company. Rick?

Richard Hawkins

Thank you, Carl. We are really excited to merge with NewLink and create this new company. I would like to talk a bit more now about the strategic priorities that would result from our proposed merger, which will establish this late-stage biopharmaceutical company with the objective of providing treatments for rare diseases with important unmet needs. Both of our boards and our supportive stockholders here at Lumos have approved this transaction and are excited by its potential to position our new entity in the public markets with a strong balance sheet and a product candidate with significant potential. Our initial focus will be to advance LUM-201 for pediatric growth hormone deficiency, also known as PGHD, which is a Phase 2b-ready program that we plan to initiate in the middle of 2020. We will also strategically look for assets that we believe fit with our focus on rare diseases and where we believe our team has the experience, the knowhow, and wherewithal to efficiently develop and commercialize these assets.

As a combined company, we anticipate we will have pro forma cash on hand of approximately $80 million at December 31, 2019, excluding any costs to be incurred for restructuring charges and severance costs, with the potential future inflow of cash related to the priority review voucher that Carl just mentioned. We believe the pro forma cash on hand will be sufficient to support our lead program through Phase a 2b readout, and any potential inflow of cash related to the priority review voucher would offer us additional financial flexibility as we explore expansion of our pipeline or acceleration of LUM-201 into other rare indications. We are truly excited for this next step forward as a joint company, as we work towards our shared vision.

I now want to spend a few minutes to provide an overview of LUM-201 and how we view its potential to disrupt the treatment paradigm of PGHD, a growing and well-established market that's still in need of improvements over its current standard of care.

PGHD occurs due to inadequate secretion of growth hormone by the pituitary gland during childhood and can be both hereditary or acquired, although the majority of cases are idiopathic. The most obvious symptom is children failing to meet early growth trajectory milestones; additionally, disruption in metabolic processes can occur as a result and cause serious issues for these children. Epidemiology indicates that PGHD occurs in about 1 in every 3,500 children, and the current standard of care is daily subcutaneous injections of recombinant human growth hormone which can be both painful for children and challenging for caregivers.

Available market data show that global sales of recombinant human growth hormone prescribed for pediatric patients reached over 1 Billion US dollars in 2016. This market is projected to increase by a compounded annual growth rate of 3.5%, reaching a potential market of nearly 1.6 billion dollars in 2026. In 2016, 65.2% of these sales represented patients treated in the

United States, while the rest of the sales were divided up in two regions, with Japanese patients accounting for 20.6% and the remaining 14.2% of sales were divided among the five largest European Union markets. The US market is forecasted to see the strongest growth in upcoming years, a projected 4.0% compounded annual growth rate. An even higher growth rate in the US may be achieved through increased efforts to educate clinicians, patients, and the industry at large about the potential of novel therapies to improve upon current treatment regimens.

The PGHD market is well-established, with injections of recombinant human growth hormone having been in use for well over 30 years. With the average PGHD patient receiving upwards of 2,500 injections over the lifetime of treatment, both the need and desire are there to supplant therapy with a less invasive and more patient-friendly product, not only in PGHD, but potentially in a number of other indications where injectable recombinant human growth hormone is in use.

We also believe there is an established regulatory path forward for LUM-201, as we have seen a good safety profile in past pediatric studies and have the ability to use predictive enrichment markers to optimize our target patient population. LUM-201's mechanism of action, which John will dive into in just a second, relies on a functional hypothalamic-pituitary-growth hormone axis, which is present in approximately 50-60% of patients with PGHD. We believe our predictive enrichment markers, including a pharmacodynamic response to a single dose of LUM-201, should allow us to identify these patients during the screening process for our Phase 2b clinical trial, which we plan to initiate in the middle of 2020. I now want to turn the call over to our Chief Scientific Officer, John McKew, to discuss LUM-201's clinical profile. John?

John McKew

Thanks, Rick, and thanks everyone for joining us this morning. It's an exciting day and I'm really looking forward to working with the NewLink team to move this product through clinical development.

Rick briefly touched on our mechanism of action, but I'll go a bit deeper here. LUM-201, also referred to as a growth hormone secretagogue, is an agonist of the growth hormone secretagogue receptor 1a, or GHSR1a. For those who may be unfamiliar with this terminology, a secretagogue is simply a substance that stimulates the secretion or release of another substance. LUM-201's mechanism of action of stimulating growth hormone release is distinct from recombinant human growth hormone replacement therapy in that LUM-201 stimulates the body to increase the amplitude of endogenous pulsatile growth hormone secretions. Like other growth hormone secretagogues, such as the natural ligand for the growth hormone secretagogue receptor, a negative GH/IGF-1 feedback loop exists that prevents LUM-201's overstimulation of growth hormone release.

Not only may our oral candidate replace injection-based treatment regimens, but we believe LUM-201's ability to amplify an individual's own growth hormone secretion may have a positive impact on efficacy. We expect the growth hormone standard of care to move away from daily injections and progress toward a weekly injection, even though none has yet been approved. We anticipate at least one will be approved, and we believe that physicians, patients, and caregivers will appreciate LUM-201's attributes as an oral agent.

A number of studies have been conducted with LUM-201 in PGHD patients prior to our acquisition of the product candidate in July of last year. Three clinical trials in approximately 150 subjects have been conducted: one PK trial, one efficacy trial in naïve-to-treatment children, and one efficacy trial in children previously treated with recombinant human growth hormone. These clinical trials explored the safety and efficacy of LUM-201 in these patient populations. We have analyzed data from these trials and have devised a predictive enrichment marker, or PEM, strategy to select patients for inclusion in our proposed Phase 2b clinical trial. When this strategy is applied post hoc to the existing clinical data in naïve-to-treatment PGHD children, a dose response in the primary outcome measure of annualized height velocity was observed. Additionally, the annualized height velocity at the highest dose tested in this trial approached the response seen in the similarly selected PGHD patients in the recombinant human growth hormone control group. This analysis supports our plan to prospectively select patients for future efficacy trials by using the patient's pharmacodynamic response to a single dose of LUM-201, and that subject's baseline IGF-1 level, which are the two proposed Predictive Enrichment Markers, which we call "PEMs". These data have both given us confidence and helped define a clinical path forward to further develop LUM-201.

Our proposed clinical trial, pending FDA review, is a dose range finding trial in naïve-to-treatment PGHD patients that will use our predictive enrichment markers strategy to select participants in a randomized trial exploring age-matched cohorts of 0.8, 1.6, and 3.2 milligrams per kilogram per day of LUM-201 compared to a positive control arm of daily recombinant human growth hormone injections. Each arm will consist of 20 patients who will be dosed daily for six months, again using a primary outcome measure of annualized growth height velocity. A planned extension trial will enable patients who would like to continue to take the most efficacious dose of LUM-201 to transition onto a long term protocol. We believe this is a well-informed trial and are excited that this merger allows us the opportunity and additional clinical development expertise from NewLink's senior management to move LUM-201 through the clinic expeditiously and efficiently. With that, I'd like to turn the call over NewLink's Chief Medical Officer, Gene Kennedy. Gene?

Gene Kennedy

Thanks, John, and thank you all for joining us this morning. We are all very excited to announce this merger. We have been searching for a strategic opportunity for NewLink and think that LUM-201, with its differentiated mechanism of action and preliminary safety profile and efficacy signals, provides an excellent opportunity to enter a well-established market that has seen a steady growth trajectory and can potentially be expanded into other indications down the road. Some notable indications that align with our mission to bring new treatment options to patients living with rare diseases, particularly in the endocrine space where recombinant human growth hormone is approved, include Turner syndrome and children born small for gestational age, which we plan to prioritize, as well as Prader Willi syndrome and idiopathic short stature which we may explore providing funds are available. LUM-201 not only has Orphan designation for the treatment of growth hormone deficiency in the US and EU, but also has an issued US patent which expires in 2036, and patent applications in other jurisdictions.

Overall, we think LUM-201 is a valuable asset with the potential to address a meaningful established market of rare pediatric endocrine diseases. As for NewLink's clinical assets, we will continue to evaluate our oncology programs, including our Phase 1b trial in DIPG with updated results anticipated later this year. Finally, with the potential for a non-dilutive financing event through a Priority Review Voucher to be issued upon FDA approval of our partnered Ebola vaccine with Merck, we anticipate a strong balance sheet to explore further business development opportunities and drive continued growth. With that, I'd like to turn the call back over to Rick for some closing remarks. Rick?

Richard Hawkins

Thanks, Gene. To summarize, we believe the proposed merger of our companies provides an exciting path forward and excellent opportunity to build a company focused on bringing therapies to patients with rare disorders. We have the infrastructure, balance sheet, and an outstanding team behind us to capitalize on this opportunity and provide value across the board to all of our stakeholders, but most of all, to our patients. We thank you all for joining us today and look forward to updating you on our combined corporate progress following the close of the merger.

With that, we will open up the call for questions. Operator?

Operator

And our first question comes from Stephen Willey with Stifel.

Stephen Willey

Congrats on the transaction. I just have a few questions from me today. So first off, can you provide anymore information on -- on how you will plan to evaluate the assets in NewLink's pipeline in terms of future development plans? I know, you know, oncology's quite different from this rare disease portfolio, and so we're just wondering do you plan on bringing KOL's in or an outside advisor to evaluate the pipeline, and then also kind of related to that, I think you mentioned we still should expect to see year-end overall survival data from the DIPG patient population evaluant in docs one, so we're just -- I'm just wondering if that should -- will be presented at a medical conference or -- or how that information will be communicated? And then I have a follow-up. Thank you.

Gene Kennedy

Certainly. This is Gene Kennedy. Thanks for the question. I'll start with the last part first. We do hope to have the DIPG data presented later this year. Typically we do present our data at medical conferences, and if there's any announcements of, you know, data disclosures, we will make them when appropriate. As far as the rest of the NewLink oncology assets, you know, the -- the combined teams believe there's value to be had there, but we've made the intentional choice to de-emphasize them for now. Really this company is going to be focused on getting LUM-201 into the clinic and running a Phase 2B trial by the middle of 2020. That's our first goal. We think that's the most direct path to get value to patients and to give value to shareholders. That said, we will put together a process to evaluate our oncology assets and see where we can, when appropriate, build value there as well. And you said you had a follow-up?

Stephen Willey

Yes, I do. So regarding LUM-201, I'm just wondering, you know, with this oral daily option, I know that there is a weekly, you know, injectable option in the clinic, and so just wondering how you're viewing the market -- the market in terms of that potential competitor, and if patients -- if you've done some type of internal research on whether patients wouldn't prefer an oral daily versus a weekly injectable? Thank you.

John McKew

So I think the existence of the -- all of the weekly long-acting recounting human growth hormones is just a testament to -- to changes that need to happen in the standard of care in this market, and we have spent a lot of time talking to KOL's and clinicians treating kids with PGHD, and -- and they all view that, you know, long-acting weekly injections as a step forward, but I think they would all be very much more impressed with a molecule that was an oral alternative to either weekly or daily injections. So we -- we do believe there's -- there's plenty of room to -- to improve upon even a weekly standard of care.

Stephen Willey

Okay. Great. And I have one more if that's -- if that's all right. Based on some older press releases I was looking at on your website, the Lumos Haris website, I -- I read a little bit about LUM-001, and I'm just wondering if that is still in your pipeline, if there's intentions on further developing that, or if it's kind of been de-prioritized?

John McKew

So we spent a decent amount of time developing LUM-001, and we came to a conclusion that we couldn't move forward effectively with that molecule and decided to focus our resources on LUM-201.

Stephen Willey

Okay. Great. Thank you. And congrats again on the transaction.

Operator

Ladies and gentlemen, this now concludes our Q&A portion of today's conference. I'd like to turn the call over to Carl Langren for any closing remarks

Carl Langren

Again, we are very excited about this merger and the opportunity it provides us to serve patients and stockholders alike. We thank you for your interest and look forward to speaking with our investors in the months ahead.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating, you may now disconnect. Everyone, have a great day.

Additional Information about the Merger and Where to Find It

In connection with the Merger, the Company intends to file relevant materials with the Securities and Exchange Commission (the "**SEC**"), including a proxy statement for its stockholders containing the information with respect to the Merger and the Merger Agreement specified in Schedule 14A promulgated under the Securities Exchange Act of 1934, as amended and describing the proposed Merger. The proxy statement and other relevant materials (when they become available), and any other documents filed by the Company with the SEC, may be obtained free of charge at the SEC website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by the Company by directing a written request to: NewLink Genetics Corporation, 2503 South Loop Drive, Ames, IA 50010. Investors and security holders are urged to read the proxy statement and the other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

Participants in the Solicitation

The Company and its directors and executive officers and Lumos and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger will be included in the proxy statement referred to above. Additional information regarding the directors and executive officers of the Company is also included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and the proxy statement for the Company's 2019 Annual Meeting of Stockholders. These documents are available free of charge at the SEC web site (www.sec.gov) and from the Company at the address described above.

Legal Notice Regarding Forward-Looking Statements

This communication contains forward-looking statements. Forward-looking statements are generally identifiable by the use of words like “may,” “will,” “should,” “could,” “expect,” “anticipate,” “estimate,” “believe,” “intend,” or “project” or the negative of these words or other variations on these words or comparable terminology. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous factors and uncertainties outside of our control that can make such statements untrue, including, but not limited to, the Merger not being timely completed, if completed at all; prior to the completion of the Merger, the Company’s or Lumos’ respective businesses experiencing disruptions due to transaction-related uncertainty or other factors making it more difficult to maintain relationships with employees, business partners or governmental entities; the parties being unable to successfully implement integration strategies or realize the anticipated benefits of the Merger, including the possibility that the expected synergies and cost reductions from the proposed acquisition will not be realized or will not be realized within the expected time period; risks related to cost reduction efforts; the Company’s workforce reduction costs may be greater than anticipated and the workforce reduction may have an adverse impact on the Company’s development activities; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; and the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities. In addition, other factors that could cause actual results to differ materially are discussed in the Company’s filings with the SEC, including its most recent Annual Report on Form 10-K filed with the SEC, and its most recent Form 10-Q filings with the SEC. Investors and security holders are urged to read these documents free of charge on the SEC’s web site at http://www.sec.gov. The Company undertakes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise, except as required under applicable law.