

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
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material Pursuant to §240.14a-12

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 third quarter 2019 earning conference call of NewLink Genetics Corporation (“NewLink” or the “Company”).

Transcript of NewLink’s earnings call, first used or made available on November 6, 2019.

NewLink Genetics Third Quarter 2019 Earnings Conference Call

Corporate Participants

Carl W. Langren NewLink Genetics Corporation - CFO & Principal Accounting Officer

Eugene P. Kennedy NewLink Genetics Corporation - Chief Medical Officer

Lisa Miller NewLink Genetics Corporation - Director of IR

Operator

Good morning, ladies and gentlemen, and welcome to the NewLink Genetics Third Quarter 2019 Earnings Conference Call. As a reminder, this conference call is being recorded.

I will now turn the call over to Lisa Miller, Director of Investor Relations.

Lisa Miller - NewLink Genetics Corporation - Director of IR

Thank you. I'd 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 earnings release we issued this morning and in our Form 8-K, which may be accessed from the Investors page of the Company's website.

I will now turn the call over to Carl Langren, our Chief Financial Officer.

Carl W. Langren - NewLink Genetics Corporation - CFO & Principal Accounting Officer

Thank you, Lisa. Good morning, and thank you for joining us. With me today is Dr. Eugene Kennedy, Chief Medical Officer. Earlier this morning, we issued a press release reviewing our financial results for the third quarter of 2019 and recapping our previously announced intent to merge with Lumos Pharma, a private clinical-stage biopharma company focused on targeting rare and neglected diseases.

Before I run through our financials, Gene will review the key points of this proposed merger and merits of the combined companies' lead product candidate, LUM-201. Additional information regarding the proposed merger may be found in the proxy once it has been filed. Gene?

Eugene P. Kennedy - NewLink Genetics Corporation - Chief Medical Officer

Thanks, Carl, and good morning, everyone. Should our proposed merger close as anticipated, the initial focus of our combined company, which would operate as Lumos Pharma, will be to advance the lead candidate, LUM-201, for pediatric growth hormone deficiency, or PGHD. I'll take just a minute or two to discuss LUM-201 and how we view its potential to disrupt the treatment paradigm of PGHD, a well established but growing market that's still in need of improvements over its current standard of care.

LUM-201 is a Phase IIb ready program for which we would plan to start a clinical trial in PGHD in mid-2020. PGHD occurs due to inadequate secretion of growth hormone by the pituitary gland during childhood and can be either hereditary or acquired, although the majority of cases are idiopathic. The most obvious symptom is children failing to meet early growth trajectory milestones. The disruption of metabolic processes can also occur as a result of PGHD and cause serious issues for these children.

As to the PGHD market, published reports indicate that the incidence of PGHD in the U.S. alone is approximately 1 in 3,500 children. For well over 30 years, standard-of-care therapy for PGHD has consisted of daily injections of recombinant human growth hormone. Available market data show that global sales of recombinant human growth hormone prescribed for pediatric patients reached over USD 1 billion in 2016. With the average PGHD patient receiving upwards of 2,500 injections over the

lifetime of treatment, we believe strongly in the potential of LUM-201, an orally administered agent, to become a preferred therapeutic for children with PGHD.

LUM-201 has been previously studied in clinical trials involving approximately 1,200 total subjects, including approximately 150 children with PGHD. We have analyzed data from these patients and have devised a predictive enrichment marker, or PEM, strategy to select patients for inclusion in our proposed Phase 2b clinical trial. Unlike injections of recombinant human growth hormone, which act as a replacement for the inadequate production of the body's own hormone in patients with an intact pituitary axis, LUM-201 stimulates and increases the body's own growth hormone production. Therefore, we plan to use the patients' pharmacodynamic response to a single dose of LUM-201 and the patients' baseline insulin-like growth factor, or IGF-1, level as the two proposed predictive enrichment markers, or what we call PEMs. When this strategy is applied post hoc to the existing clinical data in treatment-naïve PGHD patients, a dose response in the primary outcome measure of annualized height velocity was observed.

Additionally, the annualized height velocity at the highest dose evaluated in this study approached the response seen in the similarly selected PGHD patients in the injectable recombinant human growth hormone control group. This analysis supports our plan to prospectively select patients for your future efficacy studies. These data and the well-established regulatory path followed by multiple agents previously approved in PGHD have given -- have both given us confidence and helped define a clinical path forward to develop LUM-201.

In addition, the combined company plans to evaluate additional indications for which recombinant human growth hormone has been approved, including Turner Syndrome and children born Small for Gestational Age being the first two we plan to prioritize.

Before I turn the call back over to Carl, I would like to briefly mention that on September 17, 2019, Merck announced that the FDA has accepted the BLA for our partnered Ebola vaccine, V920, and the PDUFA, or target action date, is set for March 14, 2020. We were also pleased to see in October, subsequent to that announcement, that the European Medicines Agency, or EMA, Committee for Medicinal Products for Human Use recommended a conditional marketing authorization for the vaccine. This committee recommendation will now be reviewed by the European Commission, and if the recommendation is affirmed, a centralized marketing authorization of the vaccine, brand name, ERVEBO, will be granted under a unified label in 31 European countries, supporting the urgency in addressing the deadly illness. If the vaccine receives approval by FDA, a priority review voucher will be issued, in which we own a substantial interest and which we plan to monetize.

Updated Phase 1b results for indoximod, our IDO pathway inhibitor from the cohort of pediatric patients with newly diagnosed treatment-naïve diffuse intrinsic pontine glioma, or DIPG, has been accepted for presentation at the upcoming ESMO Immuno-Oncology Congress 2019 in December in Geneva. NewLink expects to continue to evaluate its oncology portfolio to determine value-creation opportunities.

With that, I will turn the call back over to Carl to walk through the third quarter financials. Carl?

Carl W. Langren - NewLink Genetics Corporation - CFO & Principal Accounting Officer

On September 30, 2019, we announced adoption of a restructuring plan to reduce our headcount by approximately 60% to align with future priorities and to conserve resources. In conjunction with the restructuring and the departures of our former CEO and President, the Company recorded restructuring and severance charges of \$4.5 million during the third quarter.

We ended the third quarter of 2019 with cash and cash equivalents totaling \$98.5 million compared to \$120.7 million as of December 31, 2018. During the third quarter of 2019, research and development expenses were \$7 million, a decline from \$7.6 million for the same period in 2018.

General and administrative expenses in the third quarter of 2019 were \$8.3 million, up from \$7.6 million for the same period in 2018. The increase was due primarily to increases in restructuring and severance expense and in legal and consulting expense, offset partially by decreases in stock compensation, personnel-related and supplies expenses.

The Company reported a net loss of \$14.5 million or \$0.39 per diluted share for the third quarter of 2019 compared to a net loss of \$7.4 million or \$0.20 per diluted share for the third quarter of 2018. The Company ended Q3 2019 with approximately 37.3 million shares outstanding. Please refer to the press release we issued this morning for more detail on third quarter financial results.

We would also ask everyone to refer to the proxy, once it is filed, for more information regarding the proposed merger. We look forward to speaking to investors in the coming months.

And with that, I will conclude today's call. Thank you for your interest.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.

Additional Information about the Merger and Where to Find It

In connection with the proposed merger (the "**Merger**") among NewLink, Cyclone Merger Sub, Inc., a Delaware corporation and 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, 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.