

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 31, 2018 (July 26, 2018)

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

Delaware
(State or other jurisdiction
of incorporation)

001-35342
(Commission
File Number)

42-1491350
(IRS Employer
Identification No.)

2503 South Loop Drive
Ames, IA
(Address of principal executive offices)

50010
(Zip Code)

Registrant's telephone number, including area code: **(515) 296-5555**

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On July 31, 2018, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the second quarter ended June 30, 2018 ("Press Release").

A copy of the Press Release and the Second Quarter Financial Results Presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this Current Report, including Exhibits 99.1 and 99.2 attached hereto is furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 2.05. Costs Associated with Exit or Disposal Activities.

On July 26, 2018, the Board of Directors of the Company approved, and management commenced and completed on July 26, 2018, a restructuring plan to reduce operating costs and better align its workforce with the needs of its business. The objective of the restructuring is to focus the Company's resources on indoximod clinical programs for recurrent pediatric brain tumors, front-line treatment of diffuse intrinsic pontine glioma (DIPG), and front-line treatment of acute myeloid leukemia (AML). The restructuring includes changes to the Company's management team described in Item 5.02 of this Current Report.

Under this plan, the Company reduced its workforce by 25 employees (approximately 30%). Affected employees are eligible to receive severance payments and outplacement services. Employees party to change of control and involuntary termination benefit agreements will continue to vest their stock options pursuant to the terms of their agreements. Certain senior executives received accelerated vesting of certain stock options, an extension to the post-termination exercise period for certain stock options and reimbursement of COBRA payments. In each case, employee severance benefits are contingent upon an affected employee's execution (and non-revocation) of a separation agreement, which includes a general release of claims against the Company. The Company expects that the workforce reduction will decrease the Company's cash payroll expense by approximately \$4.8 million annually.

In connection with the restructuring, the Company estimates that it will incur aggregate restructuring charges of approximately \$1.4 million, which will be recorded in the third quarter of 2018, related to one-time termination severance payments and other employee-related costs, excluding any amounts related to stock-based compensation expense for the acceleration of stock options and the extension of post-termination stock option exercise periods. The majority of the cash payments related to the personnel-related restructuring charges will be paid during the remainder of 2018. The charges that the Company expects to incur in connection with the workforce reduction is subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction.

This Item 2.05 contains forward-looking statements, including, but not limited to, statements related to the expected costs associated with termination benefits and the financial impact of the reduction in force. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to cost reduction efforts. In addition, 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. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018, filed with the Securities and Exchange Commission (the "SEC") on May 9, 2018, and the Company's subsequent current reports filed with the SEC. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Item 2.05 as a result of new information, future events or changes in its expectations.

Section 5 - Corporate Governance and Management

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Mr. John B. "Jack" Henneman III

Effective July 26, 2018, John B. "Jack" Henneman III was appointed to the position of Chief Administrative Officer of the Company and resigned from his position as Chief Financial Officer of the Company. Pursuant to that certain Separation and Release Agreement, dated as of July 26, 2018, between the Company and Mr. Henneman (the "Henneman Separation Agreement"), Mr. Henneman will serve as Chief Administrative Officer and provide transition assistance to the Company until the earlier of November 9, 2018 or the date Mr. Henneman's employment with the Company ends pursuant to his employment agreement with the Company dated December 31, 2015 (such date, the "Henneman Separation Date").

Under the Henneman Separation Agreement, Mr. Henneman will receive, in exchange for a general release of claims and other consideration, (a) cash severance of (i) accrued base salary and remaining accrued but unused vacation, (ii) a lump sum payment of \$42,360 on the date that the revocation period for the release of certain claims expire, (iii) a bonus for 2018 services of \$152,496 multiplied by the percentage completion of the Company's 2018 corporate goals (assuming 100% completion of Mr. Henneman's individual goals) to be paid no later than March 15, 2019 and (iv) continued payment of Mr. Henneman's current base salary for a period of twelve (12) months, beginning after the Henneman Separation Date; (b) reimbursement for COBRA premiums up to November 2019; and (c) (i) one-year of accelerated vesting of certain outstanding and unvested options to purchase Company common stock and restricted stock units ("Awards") granted pursuant to the Company's 2009 Equity Incentive Plan (the "Equity Plan") and (ii) an extension of the exercise period for vested Awards (including those accelerated pursuant to the Henneman Separation Agreement) until November 8, 2020.

The foregoing description of the terms of the Henneman Separation Agreement are qualified in their entirety by reference to the Henneman Separation Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2018.

Mr. Brian Wiley

Effective July 27, 2018, Brian Wiley's employment with the Company terminated, and he ceased to serve as the Chief Commercial Officer of the Company. In connection with Mr. Wiley's termination, the Company and Mr. Wiley entered into a Separation and Release Agreement (the "Wiley Separation Agreement"), dated as of July 26, 2018.

Under the Wiley Separation Agreement, Mr. Wiley will receive, in exchange for a general release of claims and other consideration, (a) cash severance of (i) accrued base salary and remaining accrued but unused vacation, (ii) a lump sum payment of \$18,535 on the date that the revocation period for the release of certain claims expire, (iii) a bonus for 2018 services of \$68,116 multiplied by the percentage completion of the Company's 2018 corporate goals to be paid no later than March 15, 2019 and (iv) \$166,815, representing six months of Mr. Wiley's base salary; (b) reimbursement for COBRA premiums up to January 2019; and (c) (i) one-year of accelerated vesting of certain Awards and (ii) an extension of the exercise period for vested Awards (including those accelerated pursuant to the Wiley Separation Agreement) until July 27, 2019.

The foregoing description of the terms of the Wiley Separation Agreement are qualified in their entirety by reference to the Wiley Separation Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2018.

Mr. Carl Langren

Effective July 26, 2018, the Company has appointed Carl W. Langren, age 62, Chief Financial Officer of the Company and the Company's principal financial officer.

Mr. Langren has served as the Company's Vice President of Finance since 2011 and previously served as the Chief Financial Officer of BioProtection Systems from 2005 to 2011. Prior to joining the Company, Mr. Langren served as a principal in Capital Management Solutions from 2003 to 2006, the Chief Financial Officer of Housby Mixer Group from 1998 to 2002 and as President of Iowa Machinery and Supply from 1990 to 1998. Mr. Langren also served as Chief Financial Officer of Equity Dynamics, Inc., Treasurer of DFM Corporation and tax manager with McGladrey Pullen and Company (now RSM US LLP). Mr. Langren received his B.A. from the University of Iowa.

In connection with Mr. Langren's appointment as Chief Financial Officer and principal financial officer of the Company, Mr. Langren entered into a new employment agreement with the Company, dated July 26, 2018 (the "Langren Agreement"). Pursuant to the Langren Agreement, Mr. Langren will receive an annual salary of \$358,500 with an opportunity to earn a bonus of up to 40% of his base salary. Effective August 1, 2018, Mr. Langren will be granted an option to purchase 100,000 shares of the Company's common stock under the Equity Plan. The option will vest in equal monthly installments over four years from the date of grant.

Subject to Mr. Langren's compliance with continuing obligations owed to the Company and delivery of a separation agreement and release of claims, if Mr. Langren's employment is terminated by the Company without cause, if Mr. Langren resigns for good reason or Mr. Langren suffers death or disability that prevents Mr. Langren from performing his responsibilities for a specified period of time, Mr. Langren (or his estate, as applicable) will be eligible to receive: (i) payment of an amount equal to twelve months of his base salary and (ii) twelve months of accelerated vesting of Awards granted to Mr. Langren under the Equity Plan. If Mr. Langren's employment is terminated by the Company without cause or Mr. Langren resigns for good reason, and such termination or resignation occurs within one month before, or within thirteen months after a change in control of the Company, Mr. Langren will be eligible to receive: (i) payment of eighteen months of Mr. Langren's base salary; (ii) payment of a cash bonus; and (iii) full accelerated vesting of Awards granted to Mr. Langren under the Equity Plan and a twelve-month extension of the period wherein the Awards may be exercised.

Mr. Langren will be eligible to participate in the Company's Equity Plan and the Company's 2010 Employee Stock Purchase Plan. Mr. Langren will be eligible to participate in other benefit programs generally available to all employees of the Company, including participation in the Company's 401(k) plan. For a description of the foregoing compensatory plans or arrangements, see the section entitled "Executive Compensation" in the Company's 2018 Proxy Statement, filed with the Securities and Exchange Commission on April 9, 2018 (the "2018 Proxy Statement"). The foregoing description of the terms of Mr. Langren's employment is qualified in its entirety by the terms of the Langren Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2018.

Mr. Langren previously entered into the Company's form of indemnity agreement with its directors and officers on February 16, 2012, which is incorporated herein as Exhibit 10.1.

There are no family relationships between Mr. Langren and any director or executive officer of the Company. There are no transactions in which Mr. Langren has an interest that are required to be disclosed under Item 404(a) of Regulation S-K.

Ms. Lori Lawley

Effective July 26, 2018, the Company has appointed Lori Lawley, age 34, as Vice President - Finance and Controller of the Company and the Company's principal accounting officer.

Ms. Lawley joined the Company in April 2015. At the Company, Ms. Lawley served as Manager of SEC Reporting and Accounting Policy from April 2015 until January 2017, Director of SEC and Financial Reporting from January 2017 to November 2017 and Corporate Controller from November 2017 until July 2018. Prior to joining the Company, Ms. Lawley worked as an auditor with Ernst and Young where she served in increasing capacities from 2007 through April 2015, including as Manager from October 2011 to September 2014, and Senior Manager from October 2014 until April 2015. Ms. Lawley is a licensed certified public accountant. Ms. Lawley received her Bachelor of Business Administration and Masters in Professional Accounting from the University of Texas.

In connection with Ms. Lawley's appointment as Vice President - Finance and Controller of the Company and the Company's principal accounting officer, Ms. Lawley entered into a new employment agreement with the Company, dated July 26, 2018 (the "Lawley Agreement"). Pursuant to the Lawley Agreement, Ms. Lawley will receive an annual salary of \$200,000 with an opportunity to earn a bonus of up to 25% of her base salary. Effective August 1, 2018, Ms. Lawley will be granted an option to purchase 25,000 shares of the Company's common stock under the Equity Plan. The option will vest in equal monthly installments over four years from the date of grant.

Subject to Ms. Lawley's compliance with continuing obligations owed to the Company and delivery of a separation agreement and release of claims, if Ms. Lawley's employment is terminated by the Company without cause, if Ms. Lawley resigns for good reason or Ms. Lawley suffers death or disability that prevents Ms. Lawley from performing her responsibilities for a specified period of time, Ms. Lawley (or her estate, as applicable) will be eligible to receive: (i) payment of an amount equal to six months of her base salary and (ii) twelve months of accelerated vesting of Awards granted to Ms. Lawley under the Equity Plan. If Ms. Lawley's employment is terminated by the Company without cause or Ms. Lawley resigns for good reason, and such termination or resignation occurs within one month before, or within thirteen months after a change in control of the Company,

Ms. Lawley will be eligible to receive: (i) payment of twelve months of Ms. Lawley's base salary; (ii) payment of a cash bonus; and (iii) full accelerated vesting of Ms. Lawley's Awards under the Equity Plan.

Mr. Lawley will be eligible to participate in the Company's Equity Plan and the Company's 2010 Employee Stock Purchase Plan. Ms. Lawley will be eligible to participate in other benefit programs generally available to all employees of the Company, including participation in the Company's 401(k) plan. For a description of the foregoing compensatory plans or arrangements, see the section entitled "Executive Compensation" in the Company's 2018 Proxy Statement. The foregoing description of the terms of Ms. Lawley's employment is qualified in its entirety by the terms of the Lawley Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2018.

On July 26, 2018 Ms. Lawley entered into the Company's form of indemnity agreement with its directors and officers, which is incorporated herein as Exhibit 10.1.

There are no family relationships between Ms. Lawley and any director or executive officer of the Company. There are no transactions in which Ms. Lawley has an interest that are required to be disclosed under Item 404(a) of Regulation S-K.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
10.1	Form of Indemnity Agreement by and between the Company and its directors and executive officers (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A (File No. 333-171300), filed with the Commission on November 8, 2011).
99.1	Press Release, dated July 31, 2018, entitled " NewLink Genetics Announces Clinical Plan, Reports Second Quarter 2018 Financial Results and Revises Cash Guidance "
99.2	Second Quarter 2018 Financial Results Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 31, 2018

NewLink Genetics Corporation

By: /s/ Carl W. Langren
Carl W. Langren
Its: Chief Financial Officer



FOR IMMEDIATE RELEASE

NewLink Genetics Announces Clinical Plan, Reports Second Quarter 2018 Financial Results and Revises Cash Guidance

Management to Host Conference Call Today at 4:30 p.m. ET

Ames, Iowa, July 31, 2018 -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announced its clinical plan and strategy, reported consolidated financial results for the second quarter of 2018, and revised its cash guidance.

Update on Clinical Programs

In early April, the Company announced a review of its clinical programs involving its lead immuno-oncology candidate, indoximod. This extensive review included an evaluation of available data from clinical trials sponsored by other companies, potential combination therapies with indoximod, and unmet medical need. Based on these key criteria, NewLink Genetics has focused its indoximod clinical programs on recurrent pediatric brain tumors, front-line treatment of diffuse intrinsic pontine glioma (DIPG), and front-line treatment of acute myeloid leukemia (AML). In addition, the company will continue to advance NLG802, the prodrug of indoximod with significantly higher pharmacokinetic exposure seen in [preclinical research](#).

“Indoximod’s unique mechanism of action has shown promising activity against multiple cancers and in combination with checkpoint inhibitors, radiation, chemotherapy, and vaccines,” said Dr. Charles J. Link, Jr., MD, Chairman and Chief Executive Officer. “We intend to focus on near-term opportunities where additional data can validate the importance of indoximod in areas of high unmet need.”

Recent Key Presentations

- Presented abstract [10973](#) entitled, *Front-line therapy of DIPG using the IDO pathway inhibitor indoximod in combination with radiation and chemotherapy*, during a plenary session at the American Association of Cancer Research (AACR) 2018 Annual Meeting in April, reporting on six newly diagnosed DIPG patients all of whom had completed induction radio-immunotherapy. Treatment was well tolerated with symptomatic improvement in all 6 patients. Site-reported radiographic review indicated near resolution of tumor in one patient at the end of radiotherapy and observable improvement in 5 out of 6 patients overall. A seventh patient with progressive DIPG received reirradiation combined with indoximod, which was well tolerated with symptomatic improvement and objective tumor reduction per site-reported assessment on post-treatment MRI.
- Presented abstract [3753](#) entitled, *Indoximod modulates AhR-driven transcription of genes that control immune function*, at the 2018 AACR Annual Meeting in April. Reported data show indoximod reverses the effects of low tryptophan by increasing proliferation of effector T cells, directly reprograms T regulatory cells into helper T cells and also downregulates IDO expression in dendritic cells, further supporting indoximod’s differentiated mechanism of action.
- Presented abstract [9512](#) entitled, *Phase 2 trial of the IDO pathway inhibitor indoximod plus checkpoint inhibition for the treatment of patients with advanced melanoma*, at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting in June, demonstrating an Overall Response Rate (ORR) of 55.7% and a Complete Response (CR) of 18.6% which compares favorably to historical PD-1 monotherapy data.
- Presented abstract [4015](#) entitled, *Phase 2 trial of the IDO pathway inhibitor indoximod plus gemcitabine / nab-paclitaxel for the treatment of patients with metastatic pancreas cancer*, at the 2018 ASCO Annual Meeting

in June, demonstrating a median Overall Survival (mOS) of 10.9 months and an Overall Response Rate (ORR) of 46.1%. The combination demonstrated potentially promising activity that correlated with a measurable immune response.

- Presented a [poster](#) entitled, *Radio-immunotherapy using the IDO pathway inhibitor indoximod for children with newly-diagnosed DIPG* at the International Symposium of Pediatric Neuro-Oncology (ISPNO) 2018 Annual Meeting in July. The updated Phase 1 data showed that all (10/10) front-line treatment DIPG patients, including the 6 patients previously presented at 2018 AACR Annual Meeting, demonstrated initial symptomatic improvement, and eight of ten had completed radiation, with the remaining 2 of 10 patients continuing radiotherapy. Currently, 9/10 patients remain on study, with the longest time on study of 8.5 months at the time of the report.

Anticipated Near-Term Milestones

- 2H 2018: Updated results from Phase 1b trial of indoximod plus standard-of-care chemotherapy for patients with newly diagnosed AML expected to be presented
- 2H 2018: Initial Phase 1 data from NLG802 expected to be presented
- 1H 2019: Updated results from Phase 1 trial of indoximod plus radio-chemotherapy for pediatric patients with recurrent malignant brain tumors including initial survival data expected to be presented

Organizational Changes

The company has completed an organizational realignment that will support these clinical development efforts within its current financial capacity, substantially cut future expenses, and extend its cash runway into the second half of 2021.

The organizational changes include a reduction in headcount of approximately 30%, and include the following changes to senior leadership, effective immediately:

- Jack Henneman has been appointed Chief Administrative Officer for a transition period to end with his retirement from NewLink in November 2018
- Carl Langren has been promoted to Chief Financial Officer
- Lori Lawley has been promoted to Vice President, Finance and Controller
- Brad Powers has been promoted to General Counsel

“We are grateful for the service and contributions made by Jack and all of those who have been a part of the NewLink team. This necessary transition is difficult for our company and our people, and we don’t take these changes lightly. That said, our company will focus its energies on clinical programs in the indications where patients are in the most need and with the best opportunity for clinical success,” said Nicholas Vahanian, MD, President.

Revised Cash Guidance

As a result of these measures, the company anticipates its current cash runway to extend into the second half of 2021, excluding any additional financings, proceeds from strategic alliances, the potential receipt of the priority review voucher, or expenditures related to external opportunities. The Company expects to use approximately \$10 million per quarter after completing the restructuring.

Financial Results for the Three-Month Period Ended June 30, 2018

Cash Position: NewLink Genetics ended the quarter on June 30, 2018, with cash and cash equivalents totaling \$137.1 million compared to \$158.7 million for the year ending December 31, 2017.

R&D Expenses: Research and development expenses for the second quarter of 2018 were \$12.1 million, a decrease of \$6.1 million from \$18.2 million for the same period in 2017. The decrease was due primarily to a decrease of \$5.6 million in contract research and manufacturing spend, a decrease of \$1.1 million in personnel-related and stock

compensation expense, a \$311,000 decrease in supplies, offset by an increase of \$741,000 in clinical trial expense and an increase of \$128,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses for the second quarter of 2018 were \$7.9 million, a decrease of \$1.0 million from \$8.9 million for the same period in 2017. The decrease was due to a decrease of \$313,000 of legal and consulting expense, a decrease of \$787,000 in personnel-related and stock compensation expense offset by an increase of \$182,000 in supplies and other expense.

Net Loss: NewLink Genetics reported a net loss of \$17.3 million or (\$0.47) per diluted share for the second quarter of 2018 compared to a net loss of \$16.7 million or (\$0.57) per diluted share for the second quarter of 2017.

NewLink Genetics ended the quarter with 37,198,100 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 4:30 p.m. ET today to discuss the results and to give an update on clinical and business development activities. NewLink Genetics' senior management team will host the call, which will be open to all listeners. There will also be a question and answer session following the prepared remarks.

Access to the live conference call is available by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) five minutes prior to the start of the call. The conference call will be webcast live and a link to the webcast can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in the "Investors & Media" section under "Events and Presentations" or by clicking [here](#). To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled webcast. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 4478527. The replay will be available for two weeks from the date of the call.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target, suppressing immune response and allowing for immune escape by degrading tryptophan with the resultant production of kynurenine. We hypothesize that immune activation using indoximod based combination immunotherapy can allow responsiveness to chemotherapy and radiation in patients who may otherwise be refractory or have limited benefit. The immunostimulatory effects of indoximod impact four main cell types: CD8+ T cells, CD4+ T helper cells, T regulatory cells, and dendritic cells. Indoximod reverses the effects of low tryptophan by increasing the proliferation of CD8+ effector T cells, drives differentiation into CD4+ T helper cells rather than regulatory T cells, and downregulates IDO expression in dendritic cells. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications including recurrent pediatric brain tumors, DIPG, and AML.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune system to combat cancer. For more information, please visit www.newlinkgenetics.com and follow us on Twitter [@NLNKGenetics](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private

Securities Litigation Reform Act of 1995. The words "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about NewLink Genetics' financial guidance for 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; the effects of its organizational realignment; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2017 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink Genetics' views as of any date subsequent to the date of this press release.

Investor Contact:

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Media Contact:

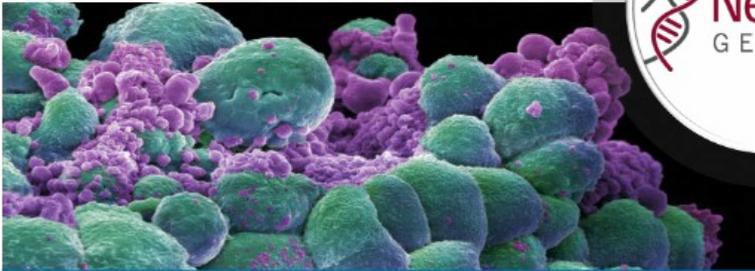
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NewLink Genetics Corporation
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Grant revenue	\$ 1,884	\$ 10,314	\$ 11,268	\$ 12,900
Licensing and collaboration revenue	368	56	884	231
Total operating revenues	<u>2,252</u>	<u>10,370</u>	<u>12,152</u>	<u>13,131</u>
Operating expenses:				
Research and development	12,088	18,200	32,402	33,925
General and administrative	7,912	8,897	16,204	17,131
Total operating expenses	<u>20,000</u>	<u>27,097</u>	<u>48,606</u>	<u>51,056</u>
Loss from operations	(17,748)	(16,727)	(36,454)	(37,925)
Other income and expense:				
Miscellaneous income (expense)	10	(109)	34	(113)
Interest income	461	117	846	202
Interest expense	(36)	(7)	(49)	(113)
Other income (expense), net	<u>435</u>	<u>1</u>	<u>831</u>	<u>(24)</u>
Net loss before taxes	(17,313)	(16,726)	(35,623)	(37,949)
Income tax benefit	—	—	—	310
Net loss	<u>\$ (17,313)</u>	<u>\$ (16,726)</u>	<u>\$ (35,623)</u>	<u>\$ (37,639)</u>
Basic and diluted loss per share	<u>\$ (0.47)</u>	<u>\$ (0.57)</u>	<u>\$ (0.96)</u>	<u>\$ (1.29)</u>
Basic and diluted average shares outstanding	37,165,529	29,225,386	37,160,334	29,219,469

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands)

	Year Ended	
	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 137,066	\$ 158,708
Prepaid expenses and other current assets	5,243	6,226
Income tax receivable	360	356
Other receivables	817	10,176
Total current assets	<u>143,486</u>	<u>175,466</u>
Property and equipment, net	4,387	5,091
Income tax receivable	140	\$ 140
Total non-current assets	<u>4,527</u>	<u>\$ 5,231</u>
Total assets	<u><u>\$ 148,013</u></u>	<u><u>\$ 180,697</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,334	\$ 9,256
Accrued expenses	8,527	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	87	92
Current portion of notes payable and obligations under capital leases	93	160
Total current liabilities	<u>16,041</u>	<u>22,031</u>
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	74	111
Deferred rent	952	998
Total long-term liabilities	<u>7,026</u>	<u>7,109</u>
Total liabilities	<u>23,067</u>	<u>29,140</u>
Stockholders' equity:		
Blank check preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at June 30, 2018 and December 31, 2017; issued and outstanding shares - 0 at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at June 30, 2018 and December 31, 2017; issued 37,285,745 and 37,168,122 at June 30, 2018 and December 31, 2017, respectively, and outstanding 37,198,100 and 37,109,556 at June 30, 2018 and December 31, 2017, respectively	373	372
Additional paid-in capital	399,018	389,786
Treasury stock, at cost: 87,645 and 58,566 shares at June 30, 2018 and December 31, 2017, respectively	(1,405)	(1,142)
Accumulated deficit	(273,040)	(237,459)
Total stockholders' equity	<u>124,946</u>	<u>151,557</u>
Total liabilities and stockholders' equity	<u><u>\$ 148,013</u></u>	<u><u>\$ 180,697</u></u>



Second Quarter 2018 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
July 31, 2018

Agenda

Introduction

- Lisa Miller, *Director of Investor Relations*

Clinical Priorities and Organizational Realignment

- Charles J. Link, Jr, MD, *Chairman, CEO & CSO*

Clinical Updates and Guidance on Timing of Data

- Eugene Kennedy, MD, *Chief Medical Officer*
- Nicholas Vahanian, MD, *President*

Comments on Organizational Plan

- Jack Henneman, *Chief Administrative Officer*

Second Quarter 2018 Financial Results

- Carl Langren, *Chief Financial Officer*

Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about NewLink Genetics' financial guidance for 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; the effects of its organizational realignment, and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink Genetics makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2017 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this presentation represent NewLink Genetics' views as of the date of this presentation. NewLink Genetics anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink Genetics' views as of any date subsequent to the date of this presentation.

Clinical Priorities

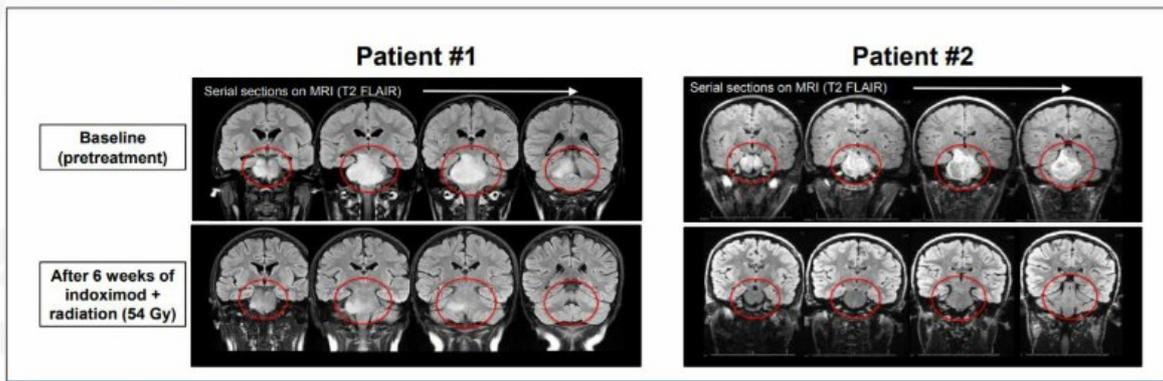
- Front-line diffuse intrinsic pontine glioma (DIPG)
 - Indoximod plus radio-chemotherapy for pediatric patients with DIPG
 - Early data show all patients demonstrated initial symptomatic improvement on therapy
 - Phase 1b trial ongoing with updated data anticipated 1H 2019
- Recurrent malignant pediatric brain tumors
 - Indoximod plus radio-chemotherapy for pediatric patients with malignant brain tumors
 - Phase 1b trial ongoing with updated data anticipated 1H 2019
- Front-line acute myeloid leukemia (AML)
 - Indoximod plus standard-of-care chemotherapy for patients with front-line AML
 - Early data show no minimal residual disease in 7/7 patients who initially responded to therapy
 - Phase 1b trial ongoing with update data anticipated 2H 2018
- NLG802, prodrug of indoximod
 - Preclinical data show significantly higher PK levels with NLG802
 - Phase 1 trial ongoing

Corporate Reorganization

- Jack Henneman appointed Chief Administrative Officer
 - To retire from NewLink Genetics November 2018
- Carl Langren promoted to Chief Financial Officer
 - Has served as Vice President of Finance
- Brad Powers promoted to General Counsel
 - Has served as Associate General Counsel
- Lori Lawley promoted to Vice President, Finance & Controller
 - Has served as Corporate Controller and head of SEC reporting
- Brian Wiley is departing as Chief Commercial Officer
 - Departing as the company refocuses on its current clinical programs
- Realigned corporate structure with reduction of workforce and related personnel costs
 - To support updated corporate strategy at significantly lower cost

Encouraging Updated DIPG Data Presented at ISPNO

Representative Imaging from the Initial MRI Results at Completion of Radiation for the First Two DIPG Patients



Reported Results for 10 DIPG Patients (ISPNO July 2, 2018)

- 9/10 remain on study
- Longest treated 8.5 months at the time of the report
- 10/10 experienced initial improvement in symptoms

Indoximod plus Chemotherapy in Acute Myeloid Leukemia (AML)

Phase 1b Exploring Minimal Residual Disease as a Surrogate Endpoint

- Phase 1b trial for patients with newly diagnosed AML
 - Combination with current standard of care (7+3 chemotherapy)
 - Currently enrolling Phase 1b expansion cohort
 - Minimal residual disease evaluated by sensitive flow cytometry assay

- Data presented by Emadi, et al at EHA, June 2017 (abstract E-012)
 - Indoximod does not appear to add significant toxicity
 - 7/9 patients who completed treatment per protocol achieved morphologic complete response (CR)
 - 7/7 patients who achieved a CR had no evidence of minimal residual disease

Financial Position

Q2 2018 End Cash and Equivalents	\$137.1 Million
Quarterly Cash Use Projected	~\$10 Million
Cash Runway Projected	~3 Years
Shares Outstanding as of June 30, 2018	37.2 Million

Key Takeaways

Indoximod, an Immuno-oncology Candidate with Differentiated MOA

- Clinical development plan for the most promising programs
 - Indoximod plus radio-chemotherapy in refractory or recurrent pediatric brain tumors
 - Indoximod plus radio-chemotherapy in front-line DIPG
 - Indoximod plus standard-of-care chemotherapy in front-line AML
 - NLG802, prodrug of indoximod
- Alignment of organization to support clinical programs within financial horizon
 - Executive and staff changes to align with prioritized clinical development programs
 - Lowered administrative and clinical development costs
- Additional indoximod data to be presented at upcoming medical conferences
 - 2H 2018: Updated Phase 1b AML data anticipated
 - 2H 2018: Initial Phase 1 data from NLG802 anticipated
 - 1H 2019: Updated Phase 1b Pediatric brain tumors data anticipated

Q & A

