

NEWLINK GENETICS CORP
Form 8-K
April 16, 2018

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): April 16, 2018 (April 11, 2018)

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

Delaware 001-35342 42-1491350
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) Identification No.)

2503 South Loop Drive 50010
Ames, IA
(Address of principal executive offices) (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 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.

On April 11, 2018, Paul Edick notified NewLink Genetics Corporation ("NewLink") that he will resign his position as a member of the board of directors of NewLink effective April 30, 2018. Mr. Edick's professional obligations have increased, and he has determined that it will not be feasible for him to continue as a member of the NewLink board. Mr. Edick served as a director of NewLink since July 2011. His resignation is not due to any disagreement with NewLink regarding any of its operations, policies or practices.

NewLink has identified a candidate for director to fill the vacancy created by Mr. Edick's resignation.

Section 8 - Other Events

Item 8.01. Other Events.

On April 15, 2018, NewLink issued a press release titled "NewLink Genetics Announces Initial Phase 1 Data with Indoximod Plus Radiation and Chemotherapy for Pediatric Patients with Diffuse Intrinsic Pontine Glioma (DIPG) Presented During AACR Plenary."

The Company has determined that it will not initiate the randomization portion of Indigo301, its study of indoximod in combination with pembrolizumab or nivolumab for patients with advanced melanoma. NewLink's clinical team will evaluate the design, trial size and feasibility of an alternative randomized evaluation of indoximod in melanoma in the context of the failure of a competitor's trial of its enzymatic IDO inhibitor in a similar clinical setting. Our evaluation will include analysis of the full data set from the Company's single-arm Phase 2 melanoma study, the differentiated mechanism of action of indoximod, and the opinions of experts in the field. The company plans to present final results from its Phase 2 melanoma trial and its single-arm Phase 2 pancreatic cancer trial at an upcoming medical meeting in the first half of this year.

Indoximod had demonstrated encouraging clinical data in other cancer indications in combination with chemotherapy, vaccines, radiotherapy, and checkpoint blockade. The company is currently evaluating the most promising indications within the indoximod program to move further into Phase 2 development.

A copy of the press release and the accompanying presentation slides are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated April 15, 2018, entitled <u>“NewLink Genetics Announces Initial Phase 1 Data with Indoximod Plus Radiation and Chemotherapy for Pediatric Patients with Diffuse Intrinsic Pontine Glioma (DIPG) Presented During AACR Plenary”</u>
99.2	<u>DIPG Presentation Slide Deck</u>

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: April 16, 2018

NewLink Genetics Corporation

By: /s/ John B. Henneman III

John B. Henneman III

Its: Chief Financial Officer