

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): November 2, 2017

**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 November 2, 2017, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the third quarter ended September 30, 2017 ("Press Release"). A copy of the Press Release and the Third 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.

**Section 9 - Financial Statements and Exhibits**

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated November 2, 2017, entitled "NewLink Genetics Corporation Reports Third Quarter 2017 Financial Results and Updates Indoximod Program"
99.2	Third Quarter 2017 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: November 2, 2017

**NewLink Genetics Corporation**

By: /s/ John B. Henneman III  
John B. Henneman III  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#"><u>Press Release, dated November 2, 2017, entitled "NewLink Genetics Corporation Reports Third Quarter 2017 Financial Results and Updates Indoximod Program"</u></a>
99.2	<a href="#"><u>Third Quarter 2017 Financial Results Presentation</u></a>



FOR IMMEDIATE RELEASE

## NewLink Genetics Reports Third Quarter 2017 Financial Results and Updates Indoximod Program

- Management to Host Conference Call Today at 8:30 a.m. ET

AMES, Iowa, November 2, 2017 -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today reported consolidated financial results for the third quarter of 2017 and provided updates on its clinical development program for indoximod, NewLink Genetics' IDO pathway inhibitor with a distinct mechanism of action.

"We are pleased with the progress we have made advancing indoximod into our pivotal trial in melanoma. Additionally, the clinical collaboration with AstraZeneca in pancreatic cancer represents a significant step toward expanding the opportunity for indoximod beyond melanoma," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer, and Chief Scientific Officer. "In addition, we have recently raised new capital in an underwritten offering which significantly increases our ability to continue to execute and expand our clinical development programs."

### Recent Highlights:

- Established the design of our pivotal trial for patients with advanced melanoma. The Phase 3 trial will evaluate indoximod in combination with both approved PD-1 checkpoint inhibitors, KEYTRUDA® (pembrolizumab) and OPDIVO® (nivolumab), in approximately 600 patients with advanced melanoma. Co-primary endpoints of the study are Progression Free Survival (PFS) by RECIST criteria and Overall Survival (OS).
- Phase 2 data for indoximod plus PD-1 checkpoint inhibitor KEYTRUDA (pembrolizumab) updated for the original 51-patient advanced melanoma cohort first presented at AACR in April demonstrated improvement in complete response rates. The Complete Response (CR) improved to 20% from 12% as the data matured, and the 12-month PFS by RECIST criteria was 56% with a median PFS (mPFS) of 12.9 months.
- Entered a clinical collaboration agreement with AstraZeneca to evaluate the combination of indoximod and IMFINZI™ (durvalumab), AstraZeneca's anti-PD-L1 monoclonal antibody, along with standard of care chemotherapy in a randomized, placebo-controlled Phase 2 trial for patients with metastatic pancreatic cancer.
- Indoximod was granted Orphan Drug Designation by the FDA for patients with Stage IIb-IV melanoma.
- Dosed the first patients with the novel salt formulation of indoximod. As planned, this was done in the ongoing Phase 1b study of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML). All subsequent trials will utilize the new formulation of indoximod.
- Raised \$55.2 million net of expenses in underwritten public offering led by Bank of America Merrill Lynch and Stifel subsequent to the third quarter. During the third quarter, we raised an additional \$19.3 million net of expenses in an "at-the-market" facility, with Cantor Fitzgerald as agent.

**Guidance for remainder of 2017 and 2018:**

- Initiate the Pivotal trial of indoximod in combination with PD-1 checkpoint blockade for patients with advanced melanoma, with the goal of enrollment by end of 2018.
- Present final results of Phase 2 trial of indoximod plus checkpoint inhibitors for patients with advanced melanoma during 2018.
- Present final results of Phase 2 trial of indoximod plus gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer at an oncology meeting 1H 2018.
- Initiate the randomized Phase 2 trial of indoximod plus durvalumab plus gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer 1H 2018.

**Financial Results for the Three-Month Period Ended September 30, 2017**

Cash Position: NewLink Genetics ended the third quarter with cash and cash equivalents totaling \$120.7 million compared to \$131.5 million for the year ending December 31, 2016.

R&D Expenses: Research and development expenses were \$18.5 million in the third quarter of 2017 compared to \$24.5 million in the third quarter of 2016. The decrease of \$6.0 million was due primarily to a \$6.2 million decline in contract research and manufacturing spend, a \$500,000 decrease in personnel-related spend, and a \$530,000 decline in clinical trial and other supplies, offset by an increase of \$630,000 in one-time restructuring expense incurred for employee severance during the third quarter of 2017, an increase in legal and consulting spend of \$370,000, and an increase in stock compensation expense of \$230,000.

G&A Expenses: General and administrative expenses in the third quarter of 2017 were \$7.9 million compared to \$7.7 million in the third quarter of 2016. The increase of \$200,000 was due to a one-time restructuring expense incurred for employee severance during the third quarter of 2017 of \$1.1 million, an increase of \$370,000 for supplies and other expenses, and an increase in stock compensation expense of \$260,000 offset by a decline of \$1.1 million in personnel-related spend, and a decline of \$430,000 in consulting and legal fees.

Net Loss: NewLink Genetics reported a net loss of \$20.6 million or \$0.69 per diluted share for the third quarter of 2017 compared to a net loss of \$15.5 million or \$0.54 per diluted share for the third quarter of 2016.

NewLink Genetics ended the quarter with 31,319,751 shares outstanding.

**Financial Guidance and Upcoming Investor Meetings**

We expect to end 2017 with approximately \$150 million in cash and equivalents.

We look forward to presenting at the Stifel Healthcare Conference in New York City on November 14<sup>th</sup> and the Jefferies Healthcare Conference in London on November 16<sup>th</sup>.

**Conference Call Details**

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to give an update. 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 can be accessed through the NewLink Genetics website at <https://edge.media-server.com/m6/p/3exk7kmc>. A replay of the call will be available

for two weeks from the date of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 6198669.

### **About Indoximod**

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape.

NewLink Genetics is currently evaluating indoximod in multiple combination studies for patients with various types of cancer including melanoma, pancreatic cancer and other malignancies.

### **About NewLink Genetics Corporation**

NewLink Genetics is a late-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. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies. For more information, please visit [www.newlinkgenetics.com](http://www.newlinkgenetics.com) and follow us on Twitter [@NLNKGenetics](https://twitter.com/NLNKGenetics).

KEYTRUDA® is a registered trademark of Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

IMFINZI™ is a registered trademark of AstraZeneca.

### **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 "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 2017; 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; 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, 2016 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:

Lisa Miller  
Director of Investor Relations  
NewLink Genetics  
(515) 598-2555  
[lmiller@linkp.com](mailto:lmiller@linkp.com)

Media Contact:

Andrew Mastrangelo  
AVP, Public & Media Relations  
LaVoieHealthScience  
617-374-8800, ext. 108  
[amastrangelo@lavoiehealthscience.com](mailto:amastrangelo@lavoiehealthscience.com)

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

	Three Months Ended September 30,		Nine Months Ended September, 30	
	2017	2016	2017	2016
Grant revenue	\$ 5,379	\$ 14,457	\$ 18,279	\$ 20,057
Licensing and collaboration revenue	103	888	334	3,008
<b>Total operating revenues</b>	<b>5,482</b>	<b>15,345</b>	<b>18,613</b>	<b>23,065</b>
Operating expenses:				
Research and development	18,480	24,463	52,405	73,810
General and administrative	7,907	7,749	25,038	26,043
<b>Loss from operations</b>	<b>(20,905)</b>	<b>(16,867)</b>	<b>(58,830)</b>	<b>(76,788)</b>
Other income, net	160	19	136	118
<b>Net loss before taxes</b>	<b>(20,745)</b>	<b>(16,848)</b>	<b>(58,694)</b>	<b>(76,670)</b>
Income tax benefit	119	1,308	429	5,021
<b>Net loss</b>	<b>\$ (20,626)</b>	<b>\$ (15,540)</b>	<b>\$ (58,265)</b>	<b>\$ (71,649)</b>
Basic and diluted loss per share	\$ (0.69)	\$ (0.54)	\$ (1.98)	\$ (2.48)
Basic and diluted average shares outstanding	29,939,823	28,983,561	29,462,226	28,911,042

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

	Year Ended	
	September 30, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 120,702	\$ 131,490
Prepaid expenses and other current assets	2,701	5,921
Income tax receivable	114	5,975
Other receivables	10,670	24,526
Total current assets	134,187	167,912
Property and equipment, net	5,527	6,835
Total assets	<u>\$ 139,714</u>	<u>\$ 174,747</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 25,692	\$ 37,192
Unearned revenue	112	391
Other current liabilities	287	322
Total current liabilities	26,091	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	138	285
Deferred rent	1,021	1,091
Total long-term liabilities	7,159	7,376
Total liabilities	33,250	45,281
Stockholders' equity:		
Common stock	314	292
Additional paid-in capital	331,036	295,535
Treasury stock, at cost	(1,113)	(853)
Accumulated deficit	(223,773)	(165,508)
Total stockholders' equity	106,464	129,466
Total liabilities and stockholders' equity	<u>\$ 139,714</u>	<u>\$ 174,747</u>



Third Quarter 2017 Results

NewLink Genetics Corporation

Nasdaq: NLNK  
November 2, 2017

# Agenda

## **Introduction**

- Jack Henneman, *Executive Vice President & CFO*

## **IDO Pathway Program Developments & Outlook**

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

## **Clinical Updates & Guidance on Timing of Data**

- Eugene P. Kennedy, M.D., *Vice President Clinical & Medical Affairs*

## **Third Quarter 2017 Financial Results & Financing**

- Mr. Henneman

## 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 any 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, 2016 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.*

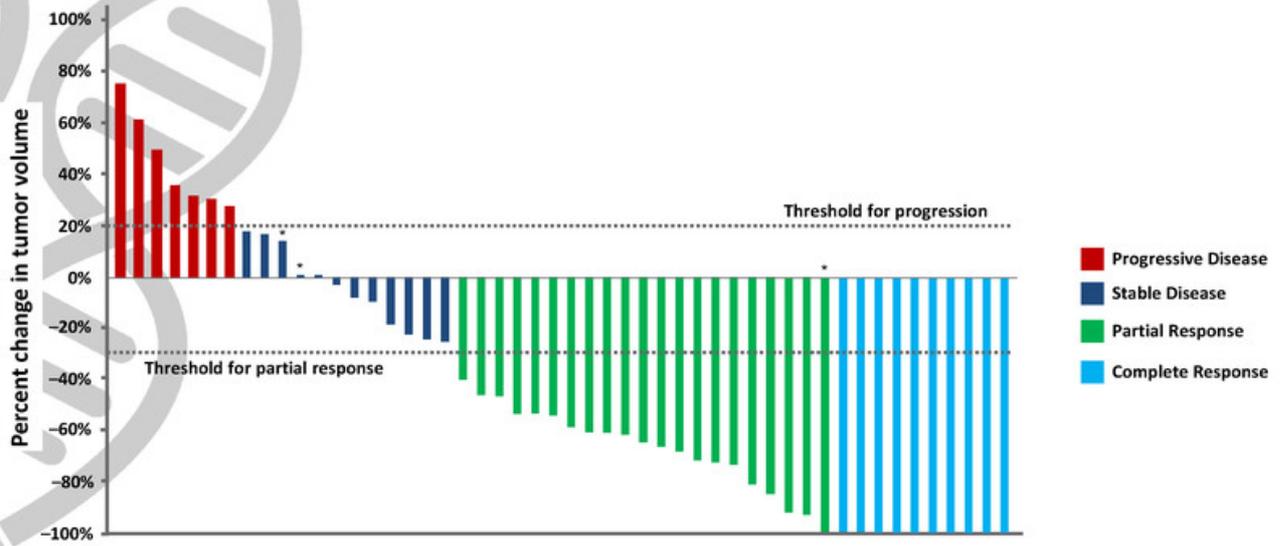
## Recent Highlights

- Progression toward Pivotal trial in advanced melanoma achieved with parameters of trial design established and reviewed by FDA
- Updated Phase 2 data for indoximod plus PD-1 checkpoint inhibitor KEYTRUDA® suggest substantial improvement of response rate for advanced melanoma patients
- Entered clinical collaboration with AstraZeneca to evaluate indoximod plus durvalumab plus standard-of-care chemotherapy in Phase 2 trial for patients with metastatic pancreatic cancer
- Indoximod granted Orphan Drug Designation by the FDA for Stage IIb-IV melanoma
- First patients dosed with novel salt formulation of indoximod
- First patients dosed with NLG802, prodrug of indoximod
- Financial position secured with ~\$55MM raised from Bank of America Merrill Lynch & Stifel led underwritten offering and \$19MM from “at the market” offering through Cantor Fitzgerald

Indoximod program has made substantial progress in 2017

# Best Response by Patient with Advanced Melanoma

## Significant Depth of Response



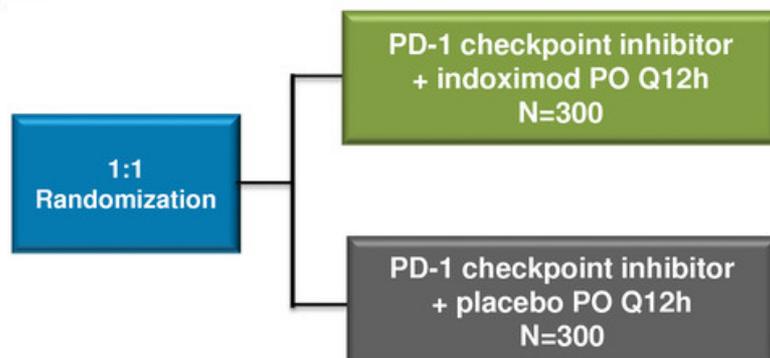
\*Patients that progressed due to new non-target lesions.

Note: 1 patient was unevaluable for response due to pleural effusion/collapsed left lung; the patient progressed based on several new non-target lesions. Zakharia Y, et al. Oral presentation at: Third International Cancer Immunology Conference; September 6-9, 2017; Frankfurt, Germany.

## Indoximod Pivotal Phase 3 Study Design

*Two-Arm, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose Study*

- Randomization via an interactive web system
- Stratified by:
  - Checkpoint inhibitor (pembro or nivo)
  - Prior BRAF treatment
  - Advanced stage disease at randomization
- Investigator choice for PD-1
  - Pembrolizumab 200mg IV Q3 weeks
  - Nivolumab 240mg IV Q2 weeks
- Treatment until disease progression or unacceptable toxicity

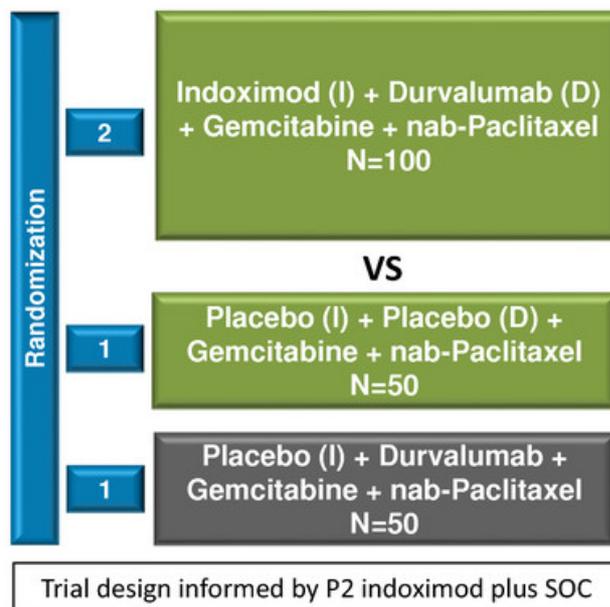


BRAF, B-Raf proto-oncogene, serine-threonine kinase; IV, intravenous; Q2W, every 2 weeks; Q3W, every 3 weeks; PO, orally; Q12h, every 12 hours.

## Clinical Collaboration between AstraZeneca and NewLink

*Phase 2 Randomized, Placebo Controlled Trial of IDO plus anti-PDL-1*

- Statistically powered to compare 4 drug regimen to Standard of Care (SOC)
- Primary Endpoint: Overall Response
- Secondary Endpoints:
  - Overall Survival
  - Progression Free Survival
  - Safety
- Status and Milestones
  - FPI 1H18
  - Protocol being finalized by Joint Committee



## Third Quarter 2017 Financial Results

Cash and Equivalents	\$120.7 million
Debt	~\$0.3 million
YE 2017 Cash (Projected) <sup>1</sup>	~\$150 million
Forecast Quarterly Negative Cash-Flow	~\$14-\$16 million
Shares Outstanding as of October 31, 2017 <sup>1</sup>	37.1 million

<sup>1</sup>Includes ~\$55 million from an underwritten offering of 5.75 million shares of stock and proceeds from 1.9 million shares of stock sold under the company's ATM

Financially well positioned to proceed with indoximod development program

## NewLink Genetics

### *Key Takeaways*

- The Phase 3 Pivotal trial for patients with advanced melanoma is our top priority and we continue to work toward our goal of completing accrual by the end of 2018.
- The AstraZeneca collaboration represents a significant step in our effort to expand the clinical program and differentiate indoximod from other IDO pathway inhibitors.
- The opportunity for indoximod has the potential to go well beyond these initial indications.



# Q & A

