NEWLINK GENETICS CORP
Form 10-Q
May 09, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

ý Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the quarterly period ended March 31, 2018.
o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the transition period from to .
Commission File Number
001-35342

NEWLINK GENETICS CORPORATION

(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated

filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x	
Non-accelerated filer o	(Do not check if a smaller reporting company)	
	Smaller reporting company o	
	Emerging growth company o	

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

As of May 7, 2018, there were 37,165,098 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

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PART I

NewLink Genetics Corporation
and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share data)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 143,891	$ 158,708
Prepaid expenses and other current assets	5,616	6,226
Income tax receivable	339	356
Other receivables	10,353	10,176
Total current assets	160,199	175,466
Property and equipment, net	4,698	5,091
Income tax receivable	140	140
Total non-current assets	4,838	5,231
Total assets	$ 165,037	$ 180,697
Liabilities and Stockholders' Equity		

Current liabilities:			
Accounts payable	$ 5,316	$ 9,256	
Accrued expenses	14,500	12,467	
Current portion of unearned revenue	—	56	
Current portion of deferred rent	90	92	
Current portion of notes payable and obligations under capital leases	112	160	
Total current liabilities	20,018	22,031	
Long-term liabilities:			
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000	
Notes payable and obligations under capital leases	90	111	
Deferred rent	975	998	

Total long-term liabilities	7,065	7,109
Total liabilities	27,083	29,140
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at March 31, 2018 and December 31, 2017; issued and outstanding shares — 0 at March 31, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at March 31, 2018	373	372

and December 31, 2017; issued 37,252,384 and 37,168,122 at March 31, 2018 and December 31, 2017, respectively, and outstanding 37,165,098 and 37,109,556 at March 31, 2018 and December 31, 2017, respectively		
Additional paid-in capital	394,711	389,786
Treasury stock, at cost: 87,286 and 58,566 shares at March 31, 2018 and December 31, 2017,	(1,403)	(1,142)

respectively			
Accumulated deficit	(255,727)		(237,459)
Total stockholders' equity	137,954		151,557
Total liabilities and stockholders' equity	$ 165,037	$	180,697

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	2017
Grant revenue	$ 9,384	$ 2,586
Licensing and collaboration revenue	516	175
Total operating revenues	9,900	2,761
Operating expenses:		
Research and development	20,314	15,725
General and administrative	8,292	8,234
Total operating expenses	28,606	23,959
Loss from operations	(18,706)	(21,198)
Other income and expense:		
Miscellaneous income (expense)	24	(4)
Interest income	385	85
Interest expense	(13)	(106)
Other income	396	(25)

(expense), net				
Net loss before taxes	(18,310)		(21,223)	
Income tax benefit	—		310	
Net loss	$	(18,310)	$	(20,913)
Basic and diluted loss per share	$	(0.49)	$	(0.72)
Basic and diluted average shares outstanding	37,155,082		29,213,488	

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
Condensed Consolidated Statement of Stockholders' Equity
(unaudited)
(In thousands, except share data)

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557
Share-based compensation	—	—	4,820	—	—	4,820
Exercise of stock options and restricted stock vested	84,262	1	105	—	—	106
Repurchase of common stock	(28,720)	—	—	(261)	—	(261)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(18,310)	(18,310)
Balance at March 31, 2018	37,165,098	$ 373	$ 394,711	$ (1,403)	$ (255,727)	$ 137,954

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Three Months Ended March 31,	
	2018	**2017**
Cash Flows From Operating Activities		
Net loss	$ (18,310)	$ (20,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	4,820	5,975
Depreciation and amortization	334	360
(Gain) Loss on sale of fixed assets	(25)	4
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	146	(3,063)
Other receivables	330	14,881
Accounts payable	(1,907)	(9,751)

and accrued expenses		
Income taxes receivable	17	(312)
Unearned revenue	(56)	(168)
Deferred rent	(25)	(22)
Net cash used in operating activities	(14,676)	(13,009)
Cash Flows From Investing Activities		
Purchase of equipment	—	(35)
Proceeds on sale of equipment	83	22
Net cash provided by (used in) investing activities	83	(13)
Cash Flows From Financing Activities		
Issuance of common stock, net of offering costs	106	63
Repurchase of common stock	(261)	(237)
Payments under capital lease	(69)	(54)

obligations and principal payments on notes payable			
Net cash used in financing activities	(224)		(228)
Net decrease in cash and cash equivalents	(14,817)		(13,250)
Cash and cash equivalents at beginning of period	158,708		131,490
Cash and cash equivalents at end of period	$ 143,891	$	118,240
Supplemental disclosure of cash flows information:			
Cash paid for interest	$ 3	$	4
(Refunds received) cash paid for taxes, net	$ (17)	$	2
Noncash financing and investing activities:			
	$ —		18

Purchased leasehold improvements and equipment in accounts payable	

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. D

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed for the purpose of developing treatments for patients with cancer and other diseases. NewLink initiated operations in April 2000.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs.

The accompanying condensed consolidated financial statements as of March 31, 2018 and for the three months ended have been prepared assuming the Company will continue as a going concern. The Company successfully raised net proceeds of $37.6 million from its IPO, completed a follow-on offering of its common stock raising net proceeds of $49.0 million, and raised an additional $58.7 million in net proceeds from an at the market (ATM) offering completed in 2015.

On November 29, 2016, the Company entered into a Sales Agreement with Cantor Fitzgerald & Co. (Cantor) under which the Company may sell up to $40.0 million of its common stock in one or more placements at prevailing market prices for its common stock (the 2016 ATM Offering). The Company launched the 2016 ATM Offering in June 2017 and under this ATM has sold 1,940,656 shares of the Company's common stock, with aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor as the placement agent, and other costs of $163,000. In October 2017, the Company sold 5,750,000 of its shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million. On March 12, 2018, the Company entered into a Sales Agreement with Cantor under which the Company may sell up to $60.0 million of its common stock in one or more placements at prevailing market prices in an ATM offering (the 2018 ATM Offering). As of March 31, 2018, no shares have been sold under the 2018 ATM Offering.

The Company's cash and cash equivalents after these agreements and the offerings are expected to be adequate to satisfy the Company's liquidity requirements into 2020. If available liquidity becomes insufficient to meet the Company’s operating obligations as they come due, the Company's plans include pursuing alternative funding arrangements and/or reducing expenditures as necessary to meet the Company’s cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company’s ability to continue as a going concern.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), and, in management’s opinion, reflect all adjustments necessary to present fairly the Company’s interim condensed financial information.

Certain information and footnote disclosures normally included in the Company’s annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2017, included in the Company’s Annual Report on Form 10-K. The financial results for any interim period are not necessarily indicative of financial results for the full year.

3. Significant Accounting Policies

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of NewLink and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable and capital lease obligations was $202,000 and $271,000 as of March 31, 2018 and December 31, 2017, respectively, which approximate fair value using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high-quality securities such as certificates of deposit and money market funds.

Property and equipment

Property and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost, less accumulated depreciation of $6.7 million and $6.6 million as of March 31, 2018 and December 31, 2017, respectively. Equipment under capital leases is stated at the present value of minimum lease payments. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years and contract manufacturing organization equipment has a useful life of five years.

Recently Issued Accounting Pronouncements not yet adopted

In February 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-02, Leases, to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheet a right of use asset and related lease liability for all leases with terms greater than twelve months. The ASU also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company does not currently have any material leases and therefore does not anticipate adoption to have a material impact on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09 (Topic 606), Revenue from Contracts with Customers. Topic 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition" (Topic 605), and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 as of January 1, 2018 and as a result changed its accounting policy for revenue recognition, as discussed in Note 4.

4. Revenues

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

On January 1, 2018, we adopted Topic 606 using the modified retrospective method by recognizing the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of equity as of January 1, 2018. Therefore results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting policy under Topic 605. The change in accounting policy from Topic 605 to Topic 606 impacted how the Company recognizes revenue from government grants, and did not impact license and collaboration revenues due to the nature of those services in the period leading up to and after the adoption of Topic 606.

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

The Company recorded an immaterial net reduction to the opening accumulated deficit within equity as of January 1, 2018 due to the cumulative impact of adopting Topic 606 with respect to grants from government entities which were not completed as of the date of adoption. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the Condensed Consolidated Balance Sheet as of January 1, 2018 (in thousands):

	As Reported December 31, 2017	Adjustments	Adjusted January 1, 2018
Balance Sheet			
Assets:			
Prepaid expenses and other current assets	$ 6,226	$ (464)	$ 5,762
Other receivables	$ 10,176	$ 506	$ 10,682
Total assets	$ 180,697	$ 42	$ 180,739
Equity:			
Accumulated deficit	$ (237,459)	$ 42	$ (237,417)
Total liabilities and stockholders' equity	$ 180,697	$ 42	$ 180,739

The impact of adoption on the Company’s Condensed Consolidated Statement of Operating Loss for the three months ended March 31, 2018 was as follows (in thousands):

	As Reported	Adjustments	Balance without Adoption of Topic 606
Statement of Operating Loss			
Grant Revenues	$ 9,384	$ (4,421)	$ 4,963
Research and Development	$ 20,314	$ 3,999	$ 16,315
Net Loss	$ (18,310)	$ 422	$ (17,888)

The impact of adoption on the Company’s Condensed Consolidated Statement of Cash Flows for the three months ended March 31, 2018 was as follows (in thousands):

	As Reported	Adjustments

					Balance without Adoption of Topic 606	
Statement of Cash Flows						
Net Loss	$	(18,310)	$	422	$	(17,888)
Changes in operating assets and liabilities:						
Other receivables	$	330	$	(4,421)	$	(4,091)
Accounts payable and accrued expenses	$	(1,907)	$	3,999	$	2,092
Net cash used in operating activities	$	(14,676)	$	—	$	(14,676)

Revenue Recognition

Revenues are recognized under Topic 606 when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The Company receives payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services. These agreements provide the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues are recognized over time and measured using the input method. The Company uses labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. This is the most faithful depiction of the transfer of goods and services to the government entities due to the government entities' control over the research and development activities. Under this method, the Company recognizes revenue

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

generally in the period during which the related costs are incurred, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

The Company had $10.0 million and $9.3 million of receivables relating to the government contracts recorded in other receivables and zero and $465,000 of unbilled expenses relating to the government contracts recorded in prepaid expenses and other current assets on the balance sheet as of March 31, 2018 and December 31, 2017, respectively. The Company had $5.5 million and $1.8 million of accrued expenses for subcontractor fees incurred under the government contracts as of March 31, 2018 and December 31, 2017, respectively.

5. License and Research Collaboration Agreements

Genentech, a Member of the Roche Group

In October 2014, the Company entered into an exclusive worldwide collaboration and license agreement with Genentech, or the Genentech Agreement, for the development and commercialization of NLG919, one of the Company's clinical stage IDO pathway inhibitors and for the discovery of next generation IDO/TDO compounds to be developed and commercialized under this agreement. Under the terms of the Genentech Agreement, the Company received a nonrefundable upfront cash payment of $150.0 million from Genentech in 2014. On June 6, 2017, we received a formal notice of Genentech’s intent to terminate the Genentech Agreement with respect to NLG919. As part of the partial termination, worldwide rights to NLG919 reverted to us, and Genentech granted to us an exclusive, royalty-bearing license under certain Genentech intellectual property to develop and commercialize NLG919. If NLG919 is commercialized, we will be obligated to pay to Genentech royalties as a low single-digit percentage of net sales of NLG919.

The Genentech Agreement continues with regards to any next generation products as defined under the Genentech Agreement and the Company is eligible to receive milestone payments of up to $561.0 million upon achieving certain development, regulatory, and sales-based milestones with respect to next generation IDO/TDO products. The Company retains the right to exercise an option to co-promote any next generation IDO/TDO products with Genentech for the U.S. market and is also eligible to receive escalating royalty payments on potential commercial sales of next generation IDO/TDO products by Genentech.

For the three months ended March 31, 2018, the Company recognized license and collaboration revenue under the Genentech Agreement of $56,000 for providing an alliance manager. For the three months ended March 31, 2017, the Company recognized license and collaboration revenue under the Genentech Agreement of $167,000 for providing an alliance manager. All of the deliverables identified within the collaboration and license agreement have been completed in their entirety and all of the $150.0 million upfront payment has been recognized as of March 31, 2018.

Merck Sharp & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement with Merck, or the Merck Agreement, to develop, manufacture and commercialilolze rVSV-ZEBOV GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada, or PHAC. Under the terms of the Merck Agreement, the Company granted Merck an exclusive, royalty bearing license to rVSV-ZEBOV GP and related technology. Under the Merck Agreement, the Company received a $30.0 million non-refundable, upfront payment in December 2014, and a one-time $20.0 million non-refundable milestone payment in February 2015 upon the initiation of the pivotal clinical trial using the current rVSV-ZEBOV GP vaccine product as one arm of the trial. In addition, the Company can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single digit to double digits on the rVSV-ZEBOV GP license agreement product sales and escalating royalties on potential commercial sales by Merck of products other than current products within the Company’s patent rights ranging from low to high single digit, on increasing levels of annual net sales worldwide. Merck will lead the development of rVSV-ZEBOV GP and any other rVSV-based viral hemorrhagic fever vaccine product candidates in order to create a marketable product safe for human use.

The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves our subsidiary, BioProtection Systems Corporation, or BPS, from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us.

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. The Company recognized license and collaboration revenues under the Merck Agreement of $460,000 and $8,000, for the reimbursement of costs not covered under government contracts for the three months ended March 31, 2018 and 2017, respectively.

6. Common Stock Equity Incentive Plan

2009 Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan, or the 2000 Plan, and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan, or the 2009 Plan. Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan are effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, the Company may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of March 31, 2018, there were 11,722,602 shares of common stock authorized for the 2009 Plan and 1,495,690 shares remained available for issuance.
The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,286
January 1, 2013	838,375
January 1, 2014	1,066,340
January 1, 2015	1,119,255
January 1, 2016	1,152,565
January 1, 2017	1,166,546
January 1, 2018	1,484,382

The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company’s stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2013 through 2018 were made pursuant to an “evergreen provision,” in accordance with which, on January 1 of each year, from 2013 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

2010 Non-Employee Directors' Stock Award Plan

Under the terms of the Company’s 2010 Non-Employee Directors’ Stock Award Plan, or the Directors’ Plan, which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of March 31, 2018, no shares remained available for issuance under the Directors' Plan.

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

2010 Employee Stock Purchase Plan

Under the terms of the Company's 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of March 31, 2018, 101,996 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three months ended March 31, 2018 and 2017 was $4.8 million and $5.9 million, respectively. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of March 31, 2018, the total compensation cost related to nonvested option awards not yet recognized was $19.8 million and the weighted-average period over which it is expected to be recognized is 2.2 years.

Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions, for the three months ended March 31, 2018:

	Number of options	Weighted average exercise price		Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,202,221	$	13.72	5.3
Options granted	1,206,414	7.82		
Options exercised	(16,760)	6.31		
Options forfeited	(7,163)	17.38		
Options expired	(15,193)	28.12		
Outstanding at end of period	8,369,519	$	12.86	5.8
Options exercisable at end of period	5,652,323	$	12.78	4.2

The Company estimates the fair value of each stock option grant on the date of grant using a Black-Scholes option pricing model. For stock option grants issued with a market condition, the Company used a Monte Carlo simulation valuation model to determine the grant date fair value.

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the three months ended March 31, 2018:

Risk-free interest rate	2.6% to 2.8%

Expected dividend yield	—%
Expected volatility	76.3% to 76.4%
Expected term (in years)	4.0 to 7.9
Weighted-average grant-date fair value per share	$5.52

The intrinsic value of options exercised during the three months ended March 31, 2018 was $34,000. The fair value of awards vested during the three months ended March 31, 2018 was $2.6 million.

During the three months ended March 31, 2018, the Company's Board of Directors approved and granted 466,750 shares of compensation and equity awards to certain executives with either market or performance conditions. The compensation and equity awards had a weighted-average grant date fair value per share of $7.85. The compensation and equity awards will vest upon the achievement of certain performance conditions. During the three months ended March 31, 2018, no performance conditions were met and zero shares were vested.

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NewLink Genetics Corporation and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for as long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are classified as equity within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's common stock on the NASDAQ Stock Market on the date of grant.

A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at March 31, 2018 and changes during the three months ended March 31, 2018 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	168,221	$ 35.82
Granted	—	—
Vested	(67,502)	34.96
Forfeited/cancelled	—	—
Unvested at end of period	100,719	$ 36.39

As of March 31, 2018, the total remaining unrecognized compensation cost related to restricted stock was approximately $3.0 million and is expected to be recognized over a weighted-average period of 1.4 years.

The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

7. Income Taxes

For the three months ended March 31, 2018, the Company recorded no income tax benefit. The income tax benefit for the three months ended March 31, 2018 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the full valuation allowance recorded against net operating losses due to the uncertainty of future recoverability. For the three months ended March 31, 2017, the Company recorded an income tax benefit of $310,000. Income tax benefit for the three months ended March 31, 2017 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the ability to carry back losses to 2015 and the net loss generated by the NewLink's foreign subsidiary. On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act repealed the two-year carryback provision for net operating losses arising after 2017, thereby reducing any benefit realized as a result of carryback to zero for the current period.

Additionally, the Company has a noncurrent income tax receivable as of March 31, 2018 for $140,000 which was recorded as an income tax benefit in 2017 and is for the receipt of AMT Credit carryovers. The Tax Act provides that AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of March 31, 2018 and December 31, 2017, respectively, due to the uncertainty of future

recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of March 31, 2018 recorded within Accrued Expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

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8. Net Loss per Common Share

Basic loss per share is based upon the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted loss per share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common stock equivalents during the period when the effect is dilutive.

The following table presents the computation of basic and diluted loss per common share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2018	2017
Loss attributable to common stockholders	$ (18,310)	$ (20,913)
Basic and diluted weighted-average shares outstanding	37,155,082	29,213,488
Basic and diluted loss per share	$ (0.49)	$ (0.72)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of March 31, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,369,519 and 100,719, respectively. As of March 31, 2017, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 7,533,695 and 219,525, respectively.

9. Restructuring Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

In July 2017, the Company undertook an organizational realignment to refocus its clinical development efforts and align the Company's resources to focus on the Company's highest value opportunities. The Company's restructuring activities included a reduction of its workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. The Company recorded total restructuring charges of $1.7 million during the year ended December 31, 2017.

There were no restructuring charges recorded during the three months ended March 31, 2018 and 2017.

The following table shows the amount accrued for restructuring activities which is recorded within Accrued Expenses in the condensed consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as	207	207

of December 31, 2017		
Expensed	—	—
Cash Payments	198	198
Balance as of March 31, 2018	9	9

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NewLink Genetics Corporation and Subsidiaries
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(unaudited)

10. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. In particular, the lead plaintiffs allege that the Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs do not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they seek to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs did not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth, or collectively, the Morrow Defendants, captioned Morrow v. Link., et al., Case 1:17-cv-03039, or the Morrow Action. The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such

proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action will be provided with any discovery that is provided in the Securities Action, and given an opportunity to participate in any mediation or settlement efforts in the Securities Action. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: our ongoing and planned preclinical studies and clinical trials; the timing of the release of the results of data from ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; plans to develop, commercialize, market and manufacture our product candidates; and other risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2017. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

NewLink Genetics Corporation (the "Company", "NewLink", "we", "our" or "us") is a clinical-stage immuno-oncology company focused on discovering and developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod, NLG802 (a prodrug of indoximod) and NLG919 (formerly navoximod or GDC-0919), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer.

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens, or TAAs. When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by IDO that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the break-down product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may also enhance the anti-tumor effects of other

immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

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IDO Pathway Inhibitors

We have a clinical development program focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include indoximod, NLG802 and NLG919. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod and NLG919 are two distinct small molecules that target the IDO pathway through different mechanisms of action and therefore could represent two different clinical and commercial opportunities. Indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the up regulation of mTOR, acts directly on T-cells, and modulates AhR-mediated effects. NLG919 and similar molecules of other companies seek to inhibit the IDO enzyme directly and thereby prevent the metabolism of tryptophan into kynurenine.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-PD-L1 or anti-CLTA4. Clinical data suggests an increase in activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with melanoma, pancreatic cancer, pediatric brain tumors, and acute myeloid leukemia. We believe there may be additional opportunities to apply indoximod to a broader set of cancer indications. Indoximod has been studied in more than 700 patients to date and has been generally well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents and a cancer vaccine.

We have finalized the dose for the salt formulation of indoximod for adult patients. Data from recent clinical trials suggest that the maximum plasma concentration levels and half-life observed after oral dosing of the new salt formulation of indoximod are modestly higher than those observed with the free base formulation.

A U.S. patent covering salt and prodrug formulations of indoximod was issued to us on August 15, 2017 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

In April 2018, we announced we would not be proceeding with Indigo301, our Phase 3 clinical trial for metastatic melanoma, due to the results of a competitor's trial of its enzymatic IDO inhibitor for patients with advanced melanoma. Indoximod has a differentiated mechanism of action (MOA) which may demonstrate clinical benefit for patients where direct enzymatic inhibitors have not. While we will not proceed with the Phase 3 clinical trial, our clinical team will be evaluating the design, trial size and feasibility of an alternative randomized study of indoximod in melanoma. This evaluation will include analysis of the full data set from our single-arm Phase 2 clinical trial of melanoma, the differentiated mechanism of action of indoximod, and the opinions of experts in the field.

In addition, we have deprioritized pancreatic cancer and have mutually agreed with AstraZeneca not to proceed with the Phase 2 clinical trial of indoximod plus durvalumab plus chemotherapy in metastatic pancreatic cancer. We have completed our own single-arm Phase 2 trial of indoximod plus chemotherapy in metastatic pancreatic cancer and expect to present the full data set in June 2018.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above the levels currently achievable by direct oral administration. We filed an Investigational New Drug application, or IND, with the FDA in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

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NLG919

NLG919, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, or the Genentech Agreement. The Genentech Agreement provided for the development and commercialization of NLG919. On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919, and such termination was effective December 6, 2017. As part of the partial termination, worldwide rights to NLG919 reverted back to the Company and Genentech granted us a license under certain of Genentech's intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities.

In addition, under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next generation IDO/tryptophan-2,3-dioxygenase, or TDO, inhibitors. The research program ended in November 2016, but our collaboration with Genentech continues with respect to next generation IDO/TDO inhibitors identified through the research program.

Additional Product Candidates

Additional clinical-stage product candidates in our pipeline include two product candidates that utilize our HyperAcute® Cellular Immunotherapy technology and two small molecules we acquired in 2017 from Daré Bioscience, Inc. (previously Cerulean Pharma Inc.). We have substantially reduced our financial commitment for the HyperAcute Cellular Immunotherapy product candidates, and have no plans to conduct additional clinical trials. We also have two other small molecules, CRLX101 and CRLX301, being evaluated in early clinical development for patients with advanced solid malignancies. Additional clinical trials with the CRLX101 product candidate is under consideration, pending the outcome of the current studies and the availability of resources.

Ebola Vaccine Candidate

In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck to develop and potentially commercialize our rVSVΔG-ZEBOV GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV GP vaccine product candidate was originally developed by the Public Health Agency of Canada, or PHAC, and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. rVSVΔG-ZEBOV GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV GP from the U.S. BioMedical Advanced Research & Development Authority, or BARDA, and the Defense Threat Reduction Agency, or DTRA, totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015, in 2017 funds of $2.1 million were de-obligated from the DTRA grant awards. We have received total awards of $118.8 million.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to novate the government grants from BARDA and DTRA to Merck. Once the novation process is complete, Merck will replace us as the prime contractor on all such grants. Until such agreement is fully executed and all contract modifications of these grants have been finalized, however, we retain the responsibility as the prime contractor

Restructuring Charges

In July 2017, we undertook an organizational realignment to refocus our clinical development efforts and align our resources to focus on our highest value opportunities. The restructuring activities included a reduction of our workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Refer to Note 9 for more information.

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Corporate Information

Founded in 1999, our principal executive office is located in Ames, Iowa, with additional offices located in Austin, Texas and Wayne, Pennsylvania. We have a clinical, research and development team dedicated to our pipeline of product candidates for patients with cancer and other diseases.

We incurred a net loss of $18.3 million for the three months ended March 31, 2018. We expect to continue to incur losses over the next several years as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with U.S. GAAP which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. As such, to understand our financial statements, it is important to understand our critical accounting policies. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

Our Annual Report on Form 10-K for the year ended December 31, 2017, discusses our most critical accounting policies. Since December 31, 2017, there have been no material changes in the critical accounting policies discussed in our 2017 Annual Report.

Recent Accounting Pronouncements

We adopted ASC Topic 606 on January 1, 2018 and have disclosed the impact adoption had on our condensed consolidated financial statements within Note 4. We do not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

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Results of Operations

Comparison of the Three Months Ended March 31, 2018 and 2017

Revenues. Revenues for the three months ended March 31, 2018 were $9.9 million, an increase of $7.1 million from $2.8 million for the same period in 2017. The increase in revenue was due to an increase in grant revenue of $6.8 million, primarily due to an increase in effort and work done by our subcontractors under the government grant contracts along with an increase in expenses recognized as revenue as a result of the adoption of ASC 606, and an increase of $341,000 in licensing revenue. Licensing revenues increased due to higher billings to Merck, offset by lower revenues recognized under the Genentech Agreement in the three months ended March 31, 2018. For the three months ended March 31, 2018 and 2017, revenues recognized under the Genentech Agreement were $56,000 and $167,000, respectively, and billings to Merck were $460,000 and $8,000 respectively.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2018 were $20.3 million, an increase of $4.6 million from $15.7 million for the same period in 2017. The increase was due primarily to an increase of $8.4 million in contract research and manufacturing spend, an increase of $670,000 in clinical trial, legal and consulting expense, offset by a $2.1 million decrease in supplies, a $1.2 million decrease in personnel-related and stock compensation expense, and a $1.2 million decrease in licensing expenses.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2018 were $8.3 million, an increase of $58,000 from $8.2 million for the same period in 2017. The increase was due to an increase of$733,000 of legal and consulting and other expense, offset by a decline of $675,000 in personnel-related and stock compensation.

Income Tax Benefit. We recorded no income tax benefit for the three months ended March 31, 2018, compared to an income tax benefit of $310,000 for the same period in 2017. The change of $310,000 is due to the ability to carry 2017 losses back to 2015. The new Tax Act, signed into effect in December 2017, ended the ability to carry losses back two years.

Net Loss. The net loss for the three months ended March 31, 2018 was $18.3 million compared to net loss of $20.9 million for the same period in 2017. The basic and diluted weighted-average common shares outstanding for the three months ended March 31, 2018 were 37,155,082, resulting in a basic and diluted loss per share of $0.49. For the three months ended March 31, 2017, the basic and diluted weighted-average common shares outstanding were 29,213,488, resulting in basic and diluted loss per share of $0.72.

Liquidity and Capital Resources

As of March 31, 2018, we had cash and cash equivalents of $143.9 million. We have funded our operations principally through the private placement of equity securities and public offerings of common stock. To date, we have raised aggregate proceeds, net of offering costs, of $76.3 million from the issuance of convertible preferred stock prior to our IPO, and $145.3 million in net proceeds through our IPO and other public follow-on offerings. Additionally, on November 29, 2016, we entered into a Sales Agreement with Cantor Fitzgerald & Co., or Cantor, under which we may sell up to $40.0 million of our common stock in one or more placements at prevailing market prices in an ATM offering. We launched this ATM in June 2017 and sold 1,940,656 shares of common stock under this ATM during 2017, with aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor as the placement agent and other expenses of $163,000. In October 2017, we sold 5,750,000 shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million. We entered into a Sales Agreement with Cantor in March 2018 under which we may sell up to $60.0 million of its common stock in one or more placements at prevailing market prices in an ATM offering (the 2018 ATM Offering). As of March 31, 2018, no shares have been sold under the 2018 ATM Offering.

With the exception of the 2014 fiscal year, we have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. We anticipate that we will continue to generate operating

losses as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

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We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research and development activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the research and development of biopharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

We believe that our cash and cash equivalents on hand will be sufficient to fund our operations into 2020.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Three Months Ended March 31,	
	2018	**2017**
Net cash used in operating activities	$ (14,676)	$ (13,009)
Net cash provided by (used in) investing activities	83	(13)
Net cash used in financing activities	(224)	(228)
Net decrease in cash and cash equivalents	$ (14,817)	$ (13,250)

For the three months ended March 31, 2018 and 2017, we used cash of $14.7 million and $13.0 million, respectively, for our operating activities. The increase in cash used in operating activities was primarily due to the increase in research and development activity, and by changes in working capital, offset by an increase in revenues for the three months ended March 31, 2018 as compared to revenues for the three months ended March 31, 2017.

For the three months ended March 31, 2018 and 2017, our investing activities provided cash of $83,000 and used cash of $13,000, respectively. The cash provided by investing activities during the three months ended March 31, 2018 was due to proceeds received from sales of property and equipment of $83,000. The cash used by investing activities during the three months ended March 31, 2017 was due to the purchase of equipment of $35,000 offset by $22,000 in proceeds received from sales of property and equipment.

For the three months ended March 31, 2018 and 2017, our financing activities used cash of $224,000 and $228,000, respectively. The cash used in financing activities during the three months ended March 31, 2018 was due to the issuance of common stock for net proceeds of $106,000 offset by net payments on long-term obligations and notes payable of $69,000 and repurchases of common stock of $261,000. The cash used in financing activities during the three months ended March 31, 2017 was primarily due to the sale and issuance of common stock for net proceeds of $63,000, offset by net payments on long-term obligations and notes payable of $54,000, and repurchase of common stock of $237,000.

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Contractual Obligations and Commitments

There are no material changes to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2018 and December 31, 2017, we had cash and cash equivalents of $143.9 million and $158.7 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial impact on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation required by the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of March 31, 2018. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of March 31, 2018, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not completed testing of any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to successfully commercialize indoximod, our business, financial condition and results of operations would be harmed.

The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

Subsequent to March 31, 2018, we announced that we will not be moving forward with Indigo301, our Phase 3 clinical trial for metastatic melanoma nor our Phase 2 clinical trial for metastatic pancreatic cancer in collaboration with AstraZeneca. We continue to review our clinical trial plans and we may decide not to move forward with other current or planned trials.

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has

shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional

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costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing Investigational New Drug applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, or we may not be able to complete them at all.

We have not completed all of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;

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- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience d