

NEWLINK GENETICS CORP

Form 10-Q

November 02, 2018

NEWLINK GENETICS CORP0001126234Accelerated

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yearsP5YP5Y2.62.9—76.279.24P7Y10M24D4.908,371,0057,314,00689,053181,3361.3800,000500,00000011262342018-01-

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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 September 30, 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 every Interactive Data File required to be submitted 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 Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

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

As of _____, the number of shares of the registrant's Common Stock, par value \$0.01 per share, outstanding is _____.

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 122,061	\$ 158,708
Prepaid expenses and other current assets	4,920	6,226
Income tax receivable	7,398	356
Other receivables	700	10,176
Total current assets	135,079	175,466
Property and equipment, net	4,096	5,091
Income tax receivable	140	140
Total non-current assets	4,236	5,231
Total assets	\$ 139,315	\$ 180,697
Liabilities and Stockholders' Equity		

Current liabilities:

Accounts payable	1,238	\$	9,256
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Accrued expenses			12,467
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Current portion of unearned revenue			56
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Current portion of deferred rent			92
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Current portion of notes payable and obligations under capital leases			160
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Total current liabilities	1,132		22,031
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Long-term liabilities:

Royalty obligation payable to Iowa	6,000		6,000
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Economic Development Authority

Notes payable and obligations under capital leases			111
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Deferred rent	929		998
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Total long-term liabilities	7,109
Total liabilities	29,140
Stockholders' equity:	
Blank check preferred stock, \$0.01 par value:	
Authorized shares — 5,000,000 at September 30, 2018 and December 31, 2017; issued and outstanding shares — 0 at September 30, 2018 and December 31, 2017	—
Common stock, \$0.01 par value:	
Authorized shares — 75,000,000 at September 30, 2018	372

and
 December
 31,
 2017;
 issued
 37,305,626
 and
 37,168,122
 at
 September
 30,
 2018
 and
 December
 31,
 2017,
 respectively,
 and
 outstanding
 37,216,892
 and
 37,109,556
 at
 September
 30,
 2018
 and
 December
 31,
 2017,
 respectively
 Additional
 paid-up capital
 403,674
 Treasury stock,
 at
 cost:
 88,734
 and
 58,566
 shares
 at
 September
 30,
 2018
 and
 December
 31,
 2017,

389,786
(1,142)

respectively

Accumulated deficit	(280,443)	(237,459)
Total stockholders' equity	151,105	151,557
Total liabilities and stockholders' equity	\$ 139,315	\$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Grant revenue	\$ —	\$ 5,379	\$ 11,268	\$ 18,279
Licensing and collaboration revenue	120	103	1,004	334
Total operating revenues	120	5,482	12,272	18,613
Operating expenses:				
Research and development	7,570	18,480	39,972	52,405
General and administrative	7,588	7,907	23,792	25,038
Total operating expenses	15,158	26,387	63,764	77,443
Loss from operations	(15,038)	(20,905)	(51,492)	(58,830)
Other income and expense:				
Miscellaneous (expense) income	(18)	12	16	(101)
Interest income	664	151	1,510	353
Interest expense	(2)	(3)	(51)	(116)
Other income	64	160	1,475	136
net				

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Net loss before taxes	(14,394)	(20,745)	(50,017)	(58,694)
Income tax benefit	6,991	119	6,991	429
Net loss	\$ (7,403)	\$ (20,626)	\$ (43,026)	\$ (58,265)
Basic and diluted loss per share	\$ (0.20)	\$ (0.69)	\$ (1.16)	\$ (1.98)
Basic and diluted average shares outstanding	37,214,363	29,939,823	37,178,542	29,462,226

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	—	—	13,620	—	—	13,620
Exercise of stock options and restricted stock vested	105,393	1	138	—	—	139
Sales of shares under stock purchase plan	32,111	—	130	—	—	130
Repurchase of common stock	(30,168)	—	—	(267)	—	(267)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(43,026)	(43,026)
Balance at September 30, 2018	37,216,892	\$ 373	\$ 403,674	\$ (1,409)	\$ (280,443)	\$ 122,195

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
Cash Flows From Operating Activities		
Net loss	\$ (43,026)	\$ (58,265)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	13,620	14,938
Depreciation and amortization	901	1,064
(Gain) Loss on sale of fixed assets	(16)	102
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	842	3,220
Other receivables	9,982	13,856
Accounts payable and accrued expenses	(11,749)	(11,500)
Income taxes receivable	(7,042)	5,861
Unearned revenue	(56)	(279)
Deferred rent	(78)	(67)
Net cash used in operating activities	(36,622)	(31,070)
Cash Flows From Investing Activities		
Purchase of equipment	(7)	(43)
Proceeds on sale of equipment	118	185

Net cash provided by investing activities	111	142		
Cash Flows From Financing Activities				
Issuance of common stock, net of offering costs	269	20,585		
Repurchase of common stock	(267)	(260)		
Payments under capital lease obligations and principal payments on notes payable	(138)	(185)		
Net cash (used in) provided by financing activities	(136)	20,140		
Net decrease in cash and cash equivalents	(36,647)	(10,788)		
Cash and cash equivalents at beginning of period	158,708	131,490		
Cash and cash equivalents at end of period	\$ 122,061	\$ 120,702		
Supplemental disclosure of cash flows information:				
Cash paid for interest	\$ 6	\$ 11		
Cash refunds received for taxes, net	\$ 4	\$ (6,261)		

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 September 30, 2018 and for the three and nine 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 initial public offering in 2011, completed a follow-on offering of its common stock raising net proceeds of \$49.0 million in 2013, and raised an additional \$58.7 million in net proceeds from an at the market (ATM) offering completed in 2015.

During 2017, the Company sold 1,940,656 shares of its common stock under an ATM offering, with aggregate net proceeds of \$19.3 million after commissions of \$398,000 paid to Cantor Fitzgerald & Co. (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 new 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 September 30, 2018, no shares have been sold under the 2018 ATM Offering.

The Company's cash and cash equivalents as of September 30, 2018 are expected to be adequate to satisfy the Company's liquidity requirements into the second half of 2021. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include selling additional shares of common stock, 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 \$133,000 and \$271,000 as of September 30, 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 \$7.1 million and \$6.6 million as of September 30, 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		Adjustments		Adjusted January
	December 31, 2017				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 and nine months ended September 30, 2018 was as follows (in thousands):

Three Months Ended September 30,						Nine Months Ended September 30,					
As Reported		Adjustments		Balance without Adoption of Topic 606		As Reported		Adjustments		Balance without Adoption of Topic 606	
Statement of Operating Loss											
Grant Revenues	—	\$	—	\$	—	\$	11,268	\$	346	\$	11,614
Licensing and collaboration revenue	120	\$	18	\$	138	\$	1,004	\$	164	\$	1,168

Research
and 7,570
Development