CareDx, Inc.
Form 10-Q
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

or

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: 001-36536

CAREDX, INC.

(Exact name of registrant as specified in its charter)

Delaware	94-3316839
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

3260 Bayshore Boulevard

Brisbane, California 94005

(Address of principal executive offices and zip code)

(415) 287-2300

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 No

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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

There were 38,901,745 shares of the registrant's Common Stock issued and outstanding as of November 5, 2018.

CareDx, Inc.

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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CareDx, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except share data)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$26,202	$16,895
Accounts receivable	9,641	2,991
Inventory	4,621	5,529
Prepaid and other assets	1,479	1,352
Total current assets	41,943	26,767
Property and equipment, net	3,022	2,075
Intangible assets, net	34,284	33,139
Goodwill	12,005	12,005
Restricted cash	192	9,579
Total assets	$91,446	$83,565
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,676	$3,391
Accrued payroll liabilities	8,017	5,013
Accrued and other liabilities	4,718	3,735
Deferred revenue	39	39
Deferred purchase consideration	367	407
Derivative liability	—	14,600
Current debt	—	15,721
Total current liabilities	15,817	42,906
Deferred rent, net of current portion	579	913
Deferred revenue, net of current portion	701	730
Deferred tax liability	3,447	4,933
Long-term debt, net of current portion	13,384	18,338
Contingent consideration	—	1,672
Common stock warrant liability	11,612	18,712
Other liabilities	1,518	1,315
Total liabilities	47,058	89,519
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding at September 30, 2018	—	—

and December 31, 2017		
Common stock: $0.001 par value; 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 38,784,111 shares and 28,825,019 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	39	29
Additional paid-in capital	356,427	264,204
Accumulated other comprehensive loss	(3,988)	(2,345)
Accumulated deficit	(308,090)	(268,022)
Total CareDx, Inc. stockholders' equity (deficit)	44,388	(6,134)
Noncontrolling interest	—	180
Total stockholders’ equity (deficit)	44,388	(5,954)
Total liabilities and stockholders’ equity	$91,446	$83,565

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CareDx, Inc.

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
Revenue:				
Testing services revenue	$16,847	$8,163	$ 41,448	$ 24,485
Product revenue	4,223	3,872	11,080	10,916
License and other revenue	114	156	532	420
Total revenue	21,184	12,191	53,060	35,821
Operating expenses:				
Cost of testing services	5,752	3,156	14,432	9,224
Cost of product	3,135	2,053	8,046	6,558
Research and development	3,868	2,959	10,732	9,360
Sales and marketing	5,971	3,255	15,916	9,747
General and administrative	5,177	4,038	16,080	14,672
Goodwill impairment	—	—	—	1,958
Change in estimated fair value of contingent consideration	—	594	1,017	309
Total operating expenses	23,903	16,055	66,223	51,828
Loss from operations	(2,719)	(3,864)	(13,163)	(16,007)
Interest expense	(408)	(1,685)	(3,527)	(4,166)
Other expense, net	(40)	(317)	(2,891)	(1,191)
Change in estimated fair value of common stock warrant liability and derivative liability	(17,093)	(8,599)	(24,540)	(3,404)
Loss before income taxes	(20,260)	(14,465)	(44,121)	(24,768)
Income tax benefit	290	178	1,095	837
Net loss	(19,970)	(14,287)	(43,026)	(23,931)
Net loss attributable to noncontrolling interest	—	(19)	(25)	(133)
Net loss attributable to CareDx, Inc.	$(19,970)	$(14,268)	$ (43,001)	$ (23,798)
Net loss per share attributable to CareDx, Inc. (Note 3):				
Basic	$(0.54)	$(0.63)	$ (1.26)	$ (1.09)
Diluted	$(0.54)	$(0.63)	$ (1.26)	$ (1.09)
Weighted average shares used to compute net loss per share attributable to CareDx, Inc.:				
Basic	37,154,293	22,526,615	34,134,138	21,765,292
Diluted	37,154,293	22,526,615	34,134,138	21,765,292

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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CareDx, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (19,970)	$ (14,287)	$ (43,026)	$ (23,931)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	117	527	(1,645)	1,461
Net comprehensive loss	(19,853)	(13,760)	(44,671)	(22,470)
Comprehensive loss attributable to noncontrolling interest, net of tax	—	(19)	(25)	(143)
Comprehensive loss attributable to CareDx, Inc.	$ (19,853)	$ (13,741)	$ (44,646)	$ (22,327)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CareDx, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2018	2017
Operating activities:		
Net loss	$(43,026)	$(23,931)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,039	2,740
Amortization of inventory fair market value adjustment	224	329
Loss on conversion of JGB Debt to shares of common stock	2,806	—
Amortization of debt discount and noncash interest expense	2,188	2,772
Revaluation of common stock warrant liability and derivative liability to estimated fair value	24,540	3,404
Stock-based compensation	5,078	1,316
Revaluation of contingent consideration to estimated fair value	1,017	309
Goodwill impairment charge	—	1,958
Changes in operating assets and liabilities:		
Accounts receivable	(3,830)	(316)
Inventory	358	462
Prepaid and other assets	(174)	(231)
Accounts payable	(863)	200
Accrued payroll liabilities	3,376	392
Accrued and other liabilities	459	(857)
Change in deferred revenue	(29)	(22)
Change in deferred taxes	(1,168)	(682)
Net cash used in operating activities	(6,005)	(12,157)
Investing activities:		
Acquisition of intangible assets through Illumina Licensing Agreement	(5,202)	—
Acquisition of Allenex AB, net of cash acquired	(692)	(502)
Acquisition of assets of Conexio Genomics Pty Ltd.	—	(467)
Purchase of property and equipment	(1,075)	(100)
Net cash used in investing activities	(6,969)	(1,069)
Financing activities:		
Proceeds from debt, net of issuance costs	14,282	24,002
Proceeds from issuance of common stock under employee stock purchase plan	32	93
Principal payments on debt and capital lease obligations	(11,397)	(13,252)
Acquisition of Conexio Genomics Pty Ltd.	(171)	—
Change in short term credit facility	(677)	581
Proceeds from exercise of warrants	10,996	35
Repurchases of common stock under employee incentive plans	(698)	—
Proceeds from exercise of stock options	589	—

Net cash provided by financing activities	12,956	11,459
Effect of exchange rate changes on cash and cash equivalents	(62)	(104)
Net decrease in cash, cash equivalents and restricted cash	(80)	(1,871)
Cash, cash equivalents, and restricted cash at beginning of period	26,474	17,401
Cash, cash equivalents, and restricted cash at end of period	$26,394	$15,530
Supplemental disclosure of cash flow information:		
Deferred purchase consideration	$—	$1,064
Shares issued in lieu of cash payment	—	1,145
Accrued interest capitalized to debt principal	—	984
Contingent consideration shares issued	2,689	—

Cash, Cash Equivalents and Restricted Cash as of:	September 30, 2018	December 31, 2017
Cash and cash equivalents	$26,202	$16,895
Restricted cash	192	9,579
Total cash, cash equivalents and restricted cash at the end of period	$26,394	$26,474

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CareDx, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc. ("CareDx" or the "Company") together with its subsidiaries, is a global transplant diagnostics company with product offerings along the pre- and post-transplant continuum. The Company focuses on discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant patients. In diagnostic testing services, the Company offers AlloMap®, which is a gene expression solution for heart transplant patients and AlloSure®, which is a donor-derived cell free DNA ("dd-cfDNA") solution initially used for kidney transplant patients. The Company also offers high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs.

AlloMap is a gene expression test that helps clinicians monitor and identify heart transplant recipients with stable graft function who have a low probability of moderate to severe acute cellular rejection. Since 2008, the Company has sought to expand the adoption and utilization of its AlloMap solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap, secure positive reimbursement decisions for AlloMap from large private and public payers, develop and enhance its relationships with key members of the transplant community, including opinion leaders at major transplant centers, and explore opportunities and technologies for the development of additional solutions for post-transplant surveillance. The Company believes the use of AlloMap, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant. In particular, the Company believes AlloMap can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and determine the appropriate dosage levels of immunosuppressants. AlloMap has received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe acute cellular rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test.

In October 2017, the Company commercially launched AlloSure, its proprietary next-generation sequencing-based test to measure dd-cfDNA after transplantation. The Company believes the use of AlloSure, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a kidney transplant. In particular, the Company believes AlloSure can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

The Company also develops, manufactures, markets and sells products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP® is used to type Human Leukocyte Antigen ("HLA") alleles, based on the sequence specific primer ("SSP") technology. Olerup SBT™ is a complete product range for sequence-based typing of HLA alleles. Olerup QTYPE® enables speed and precision in HLA typing at a low to intermediate resolution for samples that require a fast turn-around-time and uses real-time polymerase chain reaction, or PCR methodology. QTYPE received CE mark certification on April 10, 2018.

In May 2018, the Company entered into a License and Commercialization Agreement with Illumina, Inc. ("Illumina"), which provides the Company with worldwide distribution, development and commercialization rights to Illumina's next generation sequencing ("NGS") product line for use in transplantation diagnostic testing. Refer to Note 5 for additional details.

The Company changed its internal organizational structure in the third quarter of 2018 and no longer operates in two reportable segments: Post-Transplant and Pre-Transplant. The Company's Chief Operating Decision Maker ("CODM") did not change as a result of this reorganization and continues to be the Chief Executive Officer ("CEO") of the Company. Effective September 30, 2018, the Company reports in a single reportable segment. Refer to Note 16 for additional details.

The Company's headquarters are in Brisbane, California. The primary operations are in Brisbane, U.S. and Stockholm, Sweden.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $308.1 million at September 30, 2018. As of September 30, 2018, the Company had cash and cash equivalents of $26.2 million, and $13.4 million of debt outstanding, net of debt discount, under its debt obligations, of which none is current.

On April 17, 2018, the Company entered into a credit agreement with Perceptive Credit Holdings II, LP ("Perceptive") for an initial term loan of $15.0 million ("the Perceptive Credit Agreement") and repaid the outstanding indebtedness of the promissory notes previously issued to FastPartner AB and Mohammed Al Amoudi and the term loan and credit facility with Danske Bank A/S

("Danske"). A second tranche of $10.0 million will be available at the Company's option subject to the satisfaction of customary conditions. Refer to Note 10 for additional details.

The Company may require additional financing in the future to fund working capital and pay its obligations as they come due. Additional financing might include issuance of equity securities, debt, cash from collaboration agreements or a combination of these. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms favorable to the Company. The Company believes its existing cash balance and expected revenues will be sufficient to meet its anticipated cash requirements for at least the next 12 months.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies and estimates used in preparation of the unaudited condensed consolidated financial statements are described in the Company's audited consolidated financial statements as of and for the year ended December 31, 2017, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. Material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 are reflected below.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and follow the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company's financial information. The condensed consolidated balance sheet as of December 31, 2017 has been derived from audited financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated. The Company acquired CareDx International AB, formerly Allenex AB "Allenex", on April 14, 2016. Since the acquisition of Allenex through March 15, 2018, the Company owned less than 100% of the shares of Allenex and recorded a net loss attributable to noncontrolling interest in its condensed consolidated statements of operations equal to the percentage of the economic or ownership interest retained by the respective noncontrolling parties in such entities. On March 15, 2018, the Company acquired the remaining noncontrolling interest in Allenex and has not reported any noncontrolling interest balances since this date.

Use of Estimates

The preparation of unaudited 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 and the reported amounts of revenues and expenses in the unaudited

condensed consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to (i) variable transaction price consideration related to contracts with customers, (ii) the determination of the accruals for clinical studies, (iii) the fair value of assets and liabilities acquired in business combinations, including contingent consideration, (iv) inventory valuation, (v) the valuation of common stock warrant liability, (vi) the fair value of embedded derivatives, (vii) measurement of stock-based compensation expense, (viii) the determination of the valuation allowance and estimated tax benefit associated with deferred tax assets and net deferred tax liability, (ix) any impairment of long-lived assets, including in-process technology and goodwill, and (x) legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the nine months ended September 30, 2018 and 2017, approximately 47% and 27%, respectively, of total revenue was derived from Medicare. No other payers or customers represented more than 10% of total revenue for these periods.

At September 30, 2018 and December 31, 2017, approximately 29% and 16%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable on either September 30, 2018 or December 31, 2017.

Restricted Cash

A restricted cash balance of $9.4 million was released upon the full conversion of the debt obligation to JGB Collateral LLC and certain of its affiliates ("JGB") (refer to Note 10) during the three months ended March 31, 2018 and is no longer classified as restricted cash.

As a condition of the lease agreements for certain facilities and an agreement with the State of Florida Medicaid, the Company must maintain letters of credit, minimum collateral requirements and a surety bond. These agreements are collateralized by cash. The cash used to support these arrangements is classified as long-term restricted cash on the accompanying condensed consolidated balance sheets.

Common Stock Warrant Liability and Derivative Liability

Common Stock Warrant Liability

On January 1, 2018, the Company adopted Accounting Standard Update ("ASU") No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. The Company determined that the common stock warrants issued to JGB (the "JGB Warrants") meet equity classification criteria under the new standard and reclassified $6.6 million (the fair value of the JGB Warrants as of January 1, 2018) from warrant liability to equity (additional paid in capital). As of September 30, 2018, the JGB Warrants were fully exercised.

The warrant issued to Perceptive (the "Perceptive Tranche A Warrant"), on April 17, 2018, also met the equity classification as noted in Note 13. The new standard did not impact the classification of the other warrants included in the warrant liability balance as these financial instruments have other than down-round anti-dilution adjustments features.

Derivative Liability

The convertible debt financing with JGB (the "JGB Debt"), included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The combined embedded derivative was remeasured at each reporting period with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations. As of March 27, 2018, the JGB Debt was fully converted to shares of the Company's common stock. The change in the fair market value of the derivative liability through March 27, 2018 was recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations.

On April 17, 2018, the Company entered into the Perceptive Credit Agreement, which included an embedded derivative that required bifurcation related to early repayment provisions. This embedded derivative fair value of $0.2 million was recorded as debt issuance discount. Refer to Note 10 for additional details. The derivative is remeasured at the end of each reporting period if debt remains outstanding with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations.

Revenue

The Company recognizes revenue from testing services, products, and license and other revenue in the amount that reflects the consideration which it expects to be entitled in exchange for goods or services as it transfers control to its customers. Revenue is recorded considering a five-step model that includes identifying the contract with a customer,

identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation.

Testing Services Revenue

AlloMap and AlloSure patient tests are ordered by healthcare providers. The Company receives a test requisition form with payer information along with a collected patient blood sample. The Company considers the patient to be its customer and the test requisition form a contract. Testing services are performed in the Company's laboratory. Testing services represent one performance obligation in a contract and are performed when results of the test are provided to the healthcare provider, at a point of time.

The healthcare providers that order the tests and on whose behalf CareDx provides testing services are generally not responsible for the payment of these services. The first and second revenue recognition criteria are satisfied when the Company receives a test requisition form with payer information from the healthcare provider. Generally, the Company bills third-party payers upon delivery of an AlloMap or AlloSure test result to the healthcare provider. Amounts received may vary amongst payers based on coverage practices and policies of the payer. The Company has used the portfolio approach, a practical expedient under Accounting Standards Codification ("ASC") Topic 606, to identify financial classes of payers. Transaction prices are determined for each financial class

using history of reimbursements, including analysis of an average reimbursement per test and a percentage of tests reimbursed. The Company estimates revenue for non-contracted payers and self-payers using this methodology. The estimate requires significant judgment. Revenue recognized for Medicare and other contracted payers is based on the agreed current reimbursement rate per test, adjusted for historical collection trends where applicable.

The Company monitors revenue estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. As of September 30, 2018, the Company had received payments of $0.3 million more than estimated as of December 31, 2017, related to tests performed in prior periods. This change in estimate was included in testing services revenue in the three months ended September 30, 2018, when cash was collected. Changes in transaction price estimates are updated quarterly based on actual cash collected or changes made to contracted rates.

Product Revenue

Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. The Company generally has a contract or a purchase order from a customer with the specified required terms of order, including the number of products ordered. Transaction prices are determinable and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligations related to a contract and revenue is recognized at the point of delivery consistent with the terms of the contract or purchase order.

License and Other Revenue

The Company generates revenue from license agreements. License agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. The Company’s performance obligations under the agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees. The Company makes judgments to determine if performance obligations are distinct or should be combined and the transaction price allocated to each performance obligation, which affect the periods over which revenue is recognized. The Company periodically reviews its estimated periods of performance based on the progress under each arrangement and accounts for the impact of any change in estimated periods of performance on a prospective basis. The Company constrains variable consideration, such as milestones, if it is probable that a significant portion of revenue would be reversed. The Company’s deferred revenue relates to one performance obligation, which should be recognized over time.

The Company did not recognize any revenue connected with milestones during the three or nine months ended September 30, 2018 or 2017.

Cost of Testing Services

Cost of testing services reflects the aggregate costs incurred in delivering the Company’s testing services. The components of cost of testing are materials and service costs, direct labor costs, stock-based compensation, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples, and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Prior to adoption of the new revenue guidance, the Company recorded costs of testing associated with performing tests (except royalties) in the period when tests were performed without consideration of whether revenue was recognized in the same period. With the adoption of the new revenue standard on January 1, 2018, revenue and cost of testing for tests performed are recognized in the same period. Royalties for licensed

technology, calculated as a percentage of testing services revenues, are recorded as license fees in cost of testing services at the time the testing services revenues are recognized.

Recent Accounting Pronouncements

On January 1, 2018, the Company adopted the new revenue accounting standard Revenue from Contracts with Customers (Topic 606) ("ASC 606") using the modified retrospective method. The adoption of ASC 606 resulted in a one-time adjustment of $2.9 million to accounts receivable and retained earnings on January 1, 2018. The adjustment reflects the estimated payments to be received for tests where the result had been delivered at December 31, 2017, but associated revenue had not been recognized by December 31, 2017, because payment had not been received. As of September 30, 2018, the Company had received payments of $3.2 million for tests where the results had been delivered at December 31, 2017 but associated revenue had not been recognized by December 31, 2017. Payments received in excess of the $2.9 million accounts receivable adjustment recorded on January 1, 2018 were recognized in testing services revenue in the period of collection. The new standard did not impact the Company’s product revenue or license and other revenue, nor did it impact contract assets or contract liabilities.

The following table summarizes the impact of the ASC 606 adoption on accounts receivable as of September 30, 2018 (in thousands):

	Balance as Reported	Balance without the adoption of ASC 606	Impact of Adoption of ASC 606
Balance Sheets			
Accounts Receivable	$ 9,641	$ 5,734	$ 3,907

The following table summarizes the impact to the statement of operations in accordance with the new revenue standard requirements for the three and nine months ended September 30, 2018 (in thousands):

	Three Months Ended September 30, 2018		
	Balance As Reported	Balance without the adoption of ASC 606	Revenue Impact of adoption of ASC 606
Statements of Operations			
Testing revenue	$16,847	$16,561	$ 286
Product revenue	4,223	4,223	—
License and other revenue	114	114	—
	$21,184	$20,898	$ 286

	Nine Months Ended September 30, 2018		
	Balance As Reported	Balance without the adoption of ASC 606	Revenue Impact of adoption of ASC 606
Statements of Operations			
Testing revenue	$41,448	$40,637	$ 811
Product revenue	11,080	11,080	—
License and other revenue	532	532	—
	$53,060	$52,249	$ 811

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases (Topic 842) ("ASC 842"), which, for operating leases, requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases. Additionally, the FASB issued ASU, No. 2018-11, Leases (Topic 842): Targeted Improvements, which offers a practical expedient for transitioning at the adoption date. These ASUs will be effective for the Company on January 1, 2019 and the Company has chosen to use this practical expedient and recognize a cumulative-effect adjustment to the opening balance of the accumulated deficit. The Company also plans to apply other practical expedients provided by the standard. The Company has begun an implementation plan, including the identification of its lease population, the selection of a new lease software, and the implementation of changes to existing processes that will be required to implement the new lease standard. The Company believes the most significant changes to the financial statements will relate to the recognition of right-of-use assets and offsetting lease liabilities in the condensed consolidated balance sheet for operating leases. The impact on the condensed consolidated balance sheet will be contingent upon the Company's population of operating leases at adoption, however the Company does not expect the standard to have a material impact on the condensed consolidated statement of cash flows or the condensed consolidated statement of operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force) ("ASU 2016-15"), to reduce the diversity in practice with respect to the presentation of certain cash flows. The ASU is effective for interim and annual periods beginning after December 15, 2017. The Company adopted ASU 2016-15 on January 1, 2018 on a retrospective basis. The adoption of ASU 2016-15 did not have a material impact on the Company's condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force) ("ASU 2016-18"). This guidance requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash

equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for all interim and annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2016-18 on January 1, 2018 on a retrospective basis and included restricted cash together with cash and cash equivalents in its condensed consolidated statements of cash flows.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09"). The amendments provide guidance about how to account for changes to terms or conditions of a share-based payment award required under modification accounting. ASU 2017-09 is effective for all interim and annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2017-09 on January 1, 2018 on a prospective basis and the adoption of ASU 2017-09 did not have a material impact to the condensed consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 is effective for all interim and annual reporting periods beginning on or after December 15, 2018 with early adoption permitted. The Company adopted ASU 2017-11 on January 1, 2018, and the adoption resulted in the JGB common stock warrant liability balance being reclassified to additional paid in capital (Refer to Note 13).

In February 2018, the FASB issued ASU No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income ("ASU 2018-02"). The amendments in ASU 2018-02 allow a reclassification from accumulated other comprehensive income to retained earnings for certain tax effects resulting from the Tax Cuts and Jobs Act (the "Tax Act"). The Company is still reviewing the Tax Act and its impact to the condensed consolidated financial statements. ASU 2018-02 will become effective for all interim and annual reporting periods beginning after December 15, 2018 and may be applied retrospectively or as of the beginning of the period of adoption.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 is effective for all interim and annual reporting periods beginning on or after December 15, 2018. The Company will adopt ASU 2018-07 on January 1, 2019 and does not expect the adoption to have a material impact to the condensed consolidated financial statements.

3. NET LOSS PER SHARE

Basic and diluted net loss per share have been computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common share equivalents as their effect would have been antidilutive.

The following tables set forth the computation of the Company's basic and diluted net loss per share (in thousands, except shares and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				