UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 June 30, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-37369

HTG Molecular Diagnostics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**86-0912294**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3430 E. Global Loop Tucson, AZ	**85706**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (877) 289-2615

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 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 ☒ No ☐

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.

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

If an emerging growth company, indicate by check mark if he 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 August 1, 2018, the registrant had 28,421,711 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

HTG Molecular Diagnostics, Inc.
Condensed Balance Sheets

	June 30, 2018	December 31, 2017
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 5,774,356	$ 9,968,600
Short-term investments available-for-sale, at fair value	34,955,936	—
Accounts receivable	3,481,994	6,356,268
Inventory, net of allowance of $62,329 at June 30, 2018 and $62,142 at December 31, 2017	1,002,549	1,180,521
Prepaid expenses and other	845,170	443,068
Total current assets	46,060,005	17,948,457
Deferred offering costs	—	2,953
Deferred MidCap revolving loan costs	75,184	—
Property and equipment, net	2,888,995	3,304,890
Total assets	$ 49,024,184	$ 21,256,300
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,306,917	$ 2,438,798
Accrued liabilities	2,427,776	3,746,786
Contract liabilities - current	315,592	665,882
NuvoGen obligation - current	605,979	496,442
Growth Term Loan payable - net of discount and debt issuance costs	—	5,793,599
Other current liabilities	199,164	200,460
Total current liabilities	4,855,428	13,341,967
NuvoGen obligation - non-current, net of discount	6,970,277	7,520,913
Convertible note, related party - net of debt issuance costs	2,967,487	2,960,760
MidCap Term Loan payable - net of discount and debt issuance costs	6,626,886	—
Other non-current liabilities	389,490	492,197
Total liabilities	21,809,568	24,315,837
Commitments and Contingencies (Note 14)		
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2018 and December 31, 2017, 28,414,524 shares issued and outstanding at June 30, 2018 and 13,929,763 shares issued and outstanding at December 31, 2017	28,414	13,929
Additional paid-in-capital	171,246,278	131,492,595
Accumulated other comprehensive loss	(11,339)	—
Accumulated deficit	(144,048,737)	(134,566,061)
Total stockholders' equity (deficit)	27,214,616	(3,059,537)
Total liabilities and stockholders' equity (deficit)	$ 49,024,184	$ 21,256,300

See notes to the unaudited condensed financial statements.

HTG Molecular Diagnostics, Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Product and product-related services	$ 2,023,312	$ 1,458,345	$ 3,756,858	$ 2,829,514
Collaborative development services	2,887,454	302,411	5,312,560	302,411
Total revenue	4,910,766	1,760,756	9,069,418	3,131,925
Cost of revenue	1,450,682	1,236,904	2,587,745	2,532,206
Gross margin	3,460,084	523,852	6,481,673	599,719
Operating expenses:				
Selling, general and administrative	4,764,751	4,413,437	10,422,583	8,651,904
Research and development	2,758,984	1,618,889	5,348,270	2,885,952
Total operating expenses	7,523,735	6,032,326	15,770,853	11,537,856
Operating loss	(4,063,651)	(5,508,474)	(9,289,180)	(10,938,137)
Other income (expense):				
Interest expense	(233,306)	(350,058)	(415,823)	(748,478)
Interest income	197,773	17,630	330,936	29,719
Loss on extinguishment of Growth Term Loan	—	—	(105,064)	—
Total other income (expense)	(35,533)	(332,428)	(189,951)	(718,759)
Net loss before income taxes	(4,099,184)	(5,840,902)	(9,479,131)	(11,656,896)
Provision for income taxes	3,545	—	3,545	280
Net loss	$ (4,102,729)	$ (5,840,902)	$ (9,482,676)	$ (11,657,176)
Net loss per share, basic and diluted	$ (0.14)	$ (0.60)	$ (0.36)	$ (1.31)
Shares used in computing net loss per share, basic and diluted	28,375,379	9,769,322	26,549,895	8,875,177

See notes to the unaudited condensed financial statements.

HTG Molecular Diagnostics, Inc.
Condensed Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$ (4,102,729)	$ (5,840,902)	$ (9,482,676)	$ (11,657,176)
Other comprehensive income (loss), net of tax effect:				
Unrealized gain (loss) on short-term investments	(188)	736	(11,339)	1,090
Comprehensive loss	$ (4,102,917)	$ (5,840,166)	$ (9,494,015)	$ (11,656,086)

See notes to the unaudited condensed financial statements.

HTG Molecular Diagnostics, Inc.
Condensed Statement of Changes in Stockholders' Equity (Deficit)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Loss	Deficit	(Deficit)
Balance at January 1, 2018	13,929,763	$ 13,929	$131,492,595	$ -	$(134,566,061)	$ (3,059,537)
Exercise of stock options	33,651	34	69,479	—	—	69,513
Stock-based compensation expense	—	—	1,385,108	—	—	1,385,108
Vesting of restricted stock awards	269,551	270	—	—	—	270
Net share settlement of restricted stock award	(34,769)	(35)	(133,478)	—	—	(133,513)
Employee stock purchase plan	39,976	40	91,728	—	—	91,768
Issuance of common stock from ATM Offering, net of issuance costs of $17,000	261,352	261	556,445	—	—	556,706
Issuance of common stock from underwritten public offering, net of issuance costs of $2.6 million	13,915,000	13,915	37,710,401	—	—	37,724,316
MidCap Term Loan warrant discount	—	—	74,000	—	—	74,000
Net loss	—	—	—	—	(9,482,676)	(9,482,676)
Other comprehensive loss	—	—	—	(11,339)	—	(11,339)
Balance at June 30, 2018	28,414,524	$ 28,414	$171,246,278	$ (11,339)	$(144,048,737)	$27,214,616

See notes to the unaudited condensed financial statements.

HTG Molecular Diagnostics, Inc.
Condensed Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Operating activities		
Net loss	$ (9,482,676)	$ (11,657,176)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	778,344	587,466
Accretion of discount on NuvoGen obligation	(6,006)	99,377
Provision for excess inventory	23,533	244,026
Amortization of Growth Term Loan discount and issuance costs	62,951	231,319
Loss on extinguishment of Growth Term Loan	105,064	—
Amortization of QNAH Convertible Note issuance costs	6,727	—
Amortization of MidCap Credit Facility discount and issuance costs	48,092	—
Stock-based compensation expense	1,385,378	814,583
Employee stock purchase plan expense	28,906	29,223
Accretion of incentive from landlord	(71,000)	(71,000)
Accrued interest on available-for-sale securities investments	(187,946)	5,991
Changes in operating assets and liabilities:		
Accounts receivable	2,874,274	(173,427)
Inventory	191,836	(19,673)
Prepaid expenses and other	(402,102)	(35,103)
Deferred offering costs	2,953	49,630
Accounts payable	(656,645)	480,025
Accrued liabilities	(1,319,010)	(456,675)
Contract liabilities	(389,172)	278,310
Net cash used in operating activities	(7,006,499)	(9,593,104)
Investing activities		
Purchase of property and equipment	(829,186)	(152,339)
Sales, redemptions and maturities of available-for-sale securities	3,300,000	4,300,000
Purchase of available-for-sale securities	(38,079,329)	—
Net cash (used in) provided by investing activities	(35,608,515)	4,147,661
Financing activities		
Proceeds from MidCap Credit Facility	7,000,000	—
MidCap Credit Facility lender fees	(422,390)	—
Payments on Growth Term Loan	(1,684,626)	(3,126,629)
Payments for extinguishment of Growth Term Loan	(4,276,988)	—
Proceeds from public offering, net	37,932,290	—
Public offering costs	(207,974)	—
Proceeds from ATM Offering, net	556,706	14,705,770
Payments on NuvoGen obligation	(435,093)	(400,000)
Payments on capital leases	(40,017)	(24,796)
Proceeds from exercise of stock options	69,513	109,786
Taxes paid for net share settlement of restricted stock awards	(133,513)	—
Proceeds from shares purchased under the stock purchase plan	62,862	71,689
Net cash provided by financing activities	38,420,770	11,335,820
Increase (decrease) in cash and cash equivalents	(4,194,244)	5,890,377
Cash and cash equivalents at beginning of period	9,968,600	7,507,659
Cash and cash equivalents at end of period	$ 5,774,356	$ 13,398,036
Noncash investing and financing activities		
Fixed asset purchases payable and accrued at period end	$ 2,730	$ 72,224
Deferred offering costs payable and accrued at period end	—	30,000
Carrying value of demonstration units transferred from property and equipment to inventory	49,245	26,807
Equipment purchased through capital lease	45,896	—
MidCap Term Loan fees and warrant discount	389,000	—
Retirement of treasury stock	—	75,000
Supplemental cash flow information		
Cash paid for interest	$ 202,573	$ 417,782
Cash paid for taxes	3,545	280

See notes to the unaudited condensed financial statements.

Note 1. Description of Business

HTG Molecular Diagnostics, Inc. (the "Company") is a provider of instruments, reagents and services for molecular profiling applications. The Company derives revenue from sales of its HTG EdgeSeq automation system and integrated next-generation sequencing-based HTG EdgeSeq assays, from research services including sample processing and custom research use only ("RUO") assay design and from collaborative development services.

The Company operates in one segment and its customers are located primarily in the United States and Europe. For the three and six months ended June 30, 2018 approximately 74% and 76% of the Company's revenue was generated from sales originated by customers located outside of the United States, compared with 34% and 27% for the three and six months ended June 30, 2017. The increase in sales originated by customers located outside of the United States is primarily the result of collaborative development services revenue generated from the Master Assay Development, Commercialization and Manufacturing Agreement (the "Governing Agreement") with QIAGEN Manchester Limited ("QML"), a wholly owned subsidiary of QIAGEN N.V. (see Note 16), which accounted for 80% and 77% of sales to customers located outside of the United States for the three and six months ended June 30, 2018, compared to 46% and 33% for the three and six months ended June 30, 2017.

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited condensed financial statements have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and reflect the accounts of the Company as of June 30, 2018 and for the three and six months ended June 30, 2018 and 2017. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles in the United States of America ("GAAP") for complete financial statements. The accompanying interim unaudited condensed financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's financial position and the results of its operations and cash flows, as of and for the periods presented. The accompanying interim unaudited condensed balance sheet at December 31, 2017 has been derived from the audited financial statements at that date but does not include all of the information and disclosures required by GAAP for annual financial statements. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the full year. These interim unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the fiscal year ended December 31, 2017, included in the Company's Annual Report on Form 10-K filed with the SEC on March 23, 2018.

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations.

Revenue Recognition

The Company adopted the Financial Accounting Standards Board ("FASB") new revenue standard, Accounting Standards Codification 606, *Revenue from Contracts with Customers ("ASC 606"),* on January 1, 2018 using the full retrospective approach. The adoption of this standard did not have a material impact on 2017 or 2016 revenue recognition or on opening equity, as the timing and measurement of revenue recognition for the Company is materially the same under ASC 606 as it was under the prior relevant guidance.

For contracts where the period between when the Company transfers a promised good or service to the customer and when the customer pays is one year or less, the Company has elected the practical expedient to not adjust the promised amount of consideration for the effects of a significant financing component.

The Company has made a policy election to exclude from the measurement of the transaction price all taxes assessed by a government authority that are both imposed on and concurrent with a specific revenue producing transaction and collected by the Company from a customer. Such taxes may include but are not limited to sales, use, value added and certain excise taxes.

Contract Assets

Contract assets represent the Company's right to consideration in exchange for goods or services that the Company has transferred to a customer, for which rights to payment are conditional upon something other than the passage of time.

Contract Liabilities

Contract liabilities represent cash receipts for products or services to be delivered in future periods, including up-front fees received relating to custom RUO assay design and sample processing services and collaboration development services. When products or services outputs are delivered to customers, contract liabilities are recognized as earned. Up-front fees received for custom RUO assay design or collaborative development services are recognized over time based on the costs incurred to date compared to total expected costs as design or development procedures are completed and outputs are produced.

Product Warranty

The Company generally provides a one-year warranty on its HTG EdgeSeq systems covering the performance of system hardware and software in conformance with customer specifications under normal use and protecting against defects in materials and workmanship. The Company may, at its option, replace, repair or exchange products covered under valid warranty claims. This assurance-type warranty is not deemed to be a separate performance obligation under the Company's contracts with customers for the sale of instruments, as its purpose is to ensure that the product complies with agreed-upon specifications following installation of the instrument. A provision for estimated warranty costs is recognized at the time of sale, through cost of revenue, based upon recent historical experience and other relevant information as it becomes available. The Company continuously assesses the adequacy of its product warranty accrual by reviewing actual claims and adjusts the provision as needed.

Research and Development Expenses

Research and development expenses represent costs incurred internally for research and development activities and costs incurred externally to fund research activities. The costs include those generated through research and development efforts for the improvement and expansion of the Company's proprietary technology and product offerings as well as those related to third-party collaborative development agreements, for which related revenue is included in collaborative development services revenue in the accompanying interim unaudited condensed statements of operations. See Note 16 for further discussion of the development costs associated with collaborative development services agreements included in research and development expense as compared to cost of revenue in the accompanying interim unaudited condensed statements of operations.

Debt Issuance Costs

Costs incurred to issue non-revolving debt instruments are recognized as a reduction to the related debt balance in the accompanying interim unaudited condensed balance sheets and amortized to interest expense over the contractual term of the related debt using the effective interest method. Costs incurred to issue revolving debt instruments are deferred as an asset in the accompanying interim unaudited condensed balance sheets and amortized on a straight-line basis to interest expense over the term of the revolving commitment.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The Company's significant estimates include revenue recognition, stock-based compensation expense, bonus accrual, income tax valuation allowances, recovery of long-lived assets, inventory obsolescence and inventory valuation. Actual results could materially differ from those estimates.

Fair Value of Financial Instruments

The carrying value of financial instruments classified as current assets and current liabilities approximate fair value due to their liquidity and short-term nature. Investments that are classified as available-for-sale are recorded at fair value, which was determined using quoted market prices, broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. In October 2017, the Company received $3.0 million in gross proceeds from, and issued a subordinated convertible promissory note (the "QNAH Convertible Note") in that principal amount to, QIAGEN North American Holdings, Inc. ("QNAH"). As of June 30, 2018, the estimated aggregate fair value of the QNAH Convertible Note is approximately $3.4 million. The fair value estimate is based on the note's discounted cash flows and estimated option value of the conversion terms. The estimated fair value of the QNAH Convertible Note represents a Level 3 measurement. The fair value of the MidCap Term Loan (see Note 8) is also estimated using Level 3 inputs and approximates fair value as the interest rate approximates the market rate for debt securities with similar terms and

risk characteristics. The NuvoGen obligation is an obligation relating to an asset purchase transaction with a then-common stockholder of the Company. Although the obligation is considered a financial instrument, the Company is unable to reasonably determine its fair value as the remaining payments due under the obligation will be made at the greater of a minimum fixed quarterly payment or 6% of revenue, causing variability in the timing and amount of payments and the term of the obligation.

Concentration Risks

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents, available-for-sale debt securities and uncollateralized accounts receivable. The Company maintains the majority of its cash balances in the form of cash deposits in bank checking and money market accounts in amounts in excess of federally insured limits. Management believes, based upon the quality of the financial institution, that the credit risk with regard to these deposits is not significant.

The Company sells its instrument, related consumables, sample processing services, custom RUO assay design and collaborative development services primarily to biopharmaceutical companies, academic institutions and molecular labs. The Company routinely assesses the financial strength of its customers and credit losses have been minimal to date.

The Company's top three customers accounted for 59%, 11% and 5% of the Company's total revenue for the three months ended June 30, 2018, compared with 16%, 15% and 13% for the three months ended June 30, 2017. The top three customers accounted for 59%, 10% and 5% of the Company's total revenue for the six months ended June 30, 2018, compared to 16%, 12% and 9% for the six months ended June 30, 2017.

The top two customers accounted for approximately 59% and 15% of the Company's accounts receivable as of June 30, 2018, compared with approximately 66% and 11% as of December 31, 2017. The largest of these amounts represents accounts receivable relating to statements of work entered into under the Company's Governing Agreement with QML.

The Company currently relies on a single supplier to supply a subcomponent used in the HTG EdgeSeq processors. A loss of this supplier could significantly delay the delivery of processors, which in turn would materially affect the Company's ability to generate revenue.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than were required under prior GAAP.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue Recognition: Clarifying the new Revenue Standard's Principal-Versus-Agent Guidance* ("ASU 2016-08"). The standard amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09. ASU 2016-08 clarifies that an entity should evaluate whether it is the principal or the agent for each specified good or service promised in a contract with a customer. As defined in ASU 2016-08, a specified good or service is "a distinct good or service (or a distinct bundle of goods or services) to be provided to the customer." Therefore, for contracts involving more than one specified good or service, the Company may be the principal in one or more specified goods or services and the agent for others.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*. The amendments in this standard affect the guidance in ASU 2014-09 by clarifying two aspects: identifying performance obligations and the licensing implementation guidance.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow Scope Improvements and Practical Expedients.* The amendments in this standard affect the guidance in ASU 2014-09 by clarifying certain specific aspects of ASU 2014-09, including assessment of collectability, treatment of sales taxes and contract modifications, and providing certain technical corrections.

The new revenue standard and the standards that amend it were effective for public entities for fiscal years and interim periods within those fiscal years beginning after December 15, 2017, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company adopted ASC 606 as of January 1, 2018 using the full retrospective approach. The adoption of ASC 606 did not have a material impact on 2017 revenue recognition or on opening equity, as the timing and

measurement of revenue recognition is materially the same for the Company as under ASC 605. The Company has presented additional quantitative and qualitative disclosures regarding identified revenue streams and performance obligations beginning with the first quarter ended March 31, 2018 (see Note 9 and Note 16). The Company has also identified and implemented changes to its business processes and internal controls relating to implementation of the new standard.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities,* ("ASU 2016-01"), which requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. The Company adopted ASU 2016-01 as of January 1, 2018, at which time the standard did not have a significant impact on its interim unaudited condensed financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,* ("ASU 2016-15"), which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted ASU No. 2016-15 as of January 1, 2018, at which time the adoption of this standard did not have a significant impact on its interim unaudited condensed financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted ASU No. 2017-09 as of January 1, 2018. The adoption of this update did not impact the Company's interim unaudited condensed financial statements.

New Accounting Pronouncements

The following are new FASB ASUs that have not been adopted by the Company as of June 30, 2018, grouped by their respective effective dates:

January 1, 2019

In February 2016, the FASB issued ASU No. 2016-02, *Leases,* ("ASU 2016-02"). Under this standard, which applies to both lessors and lessees, lessees will be required to recognize all leases (except for short-term leases) as a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and as a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The effect of adoption of this standard on the Company's financial statements depends on the leases existing at January 1, 2019. Based on the Company's office and equipment leases currently in place and considering the practical expedients, the Company expects that adoption of ASU 2016-02 will not have a material effect on its statements of operations, will result in a gross-up on its balance sheets of less than $2.0 million relating to office and equipment leases and will have no effect on its statements of cash flows. The Company will continue to assess the new guidance and its potential applicability, to new agreements that the Company may enter into subsequent to June 30, 2018 through the date of adoption.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features*. This new standard makes limited changes to previous guidance on classifying certain financial instruments as either liabilities or equity. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years with early adoption permitted, including adoption in an interim period. When considering the Company's existing financial instruments, the Company does not believe the adoption of this standard will have an effect on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting*. The standard expands the scope of Topic 718 to include share-based payments issued to

nonemployees for goods or services, simplifying the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years with early adoption permitted, including adoption in an interim period. The Company does not believe the adoption of this standard will have a significant impact on its financial statements given the limited number of nonemployee stock-based awards outstanding.

January 1, 2020

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. Early adoption is permitted for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. The Company does not believe the adoption of this standard will have a significant impact on its financial statements, given the high credit quality of the obligors to its available-for-sale debt securities and its limited history of bad debt expense relating to trade accounts receivable.

Note 3. Inventory

Inventory, net of allowance, consisted of the following as of the dates indicated:

	June 30, 2018	December 31, 2017
Raw materials	$ 882,396	$ 984,328
Work in process	81,237	66,314
Finished goods	101,245	192,021
Total gross inventory	1,064,878	1,242,663
Less inventory allowance	(62,329)	(62,142)
	$ 1,002,549	$ 1,180,521

The reserve for shrinkage and excess inventory was $62,329 and $62,142 as of June 30, 2018 and December 31, 2017, respectively. For the three and six months ended June 30, 2018, the Company recorded adjustments in the inventory reserve of $(1,614) and $187, respectively, compared to net decreases of $66,250 and $62,427, respectively, for the three and six months ended June 30, 2017, to adjust for estimated shrinkage and obsolescence. For the three and six months ended June 30, 2018, the Company recorded adjustments to provision for excess inventory of $12,253 and $23,533, respectively. For the three and six months ended June 30, 2017, the Company recorded adjustments to provision for excess inventory of $51,599 and $244,026, respectively. Adjustments in these periods to the allowance for estimated shrinkage, obsolescence and excess inventory have been included in cost of revenue in the accompanying interim unaudited condensed statements of operations.

Note 4. Fair Value Instruments

Financial assets and liabilities measured at fair value are classified in their entirety in the fair value hierarchy based on the lowest level input significant to the fair value measurement. The following table classifies the Company's financial assets and liabilities measured at fair value on a recurring basis at June 30, 2018 and December 31, 2017, respectively:

	Balance at June 30, 2018			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 5,525,432	$ —	$ —	$ 5,525,432
Investments available-for-sale at fair value				
U.S. government obligations	$ 11,989,585	$ —	$ —	$ 11,989,585
Corporate debt securities	$ —	$ 22,966,351	$ —	$ 22,966,351
Total	$ 17,515,017	$ 22,966,351	$ —	$ 40,481,368

	Balance at December 31, 2017			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 8,521,054	$ —	$ —	$ 8,521,054
Total	$ 8,521,054	$ —	$ —	$ 8,521,054

There are no other financial instruments subject to fair value measurement on a recurring basis. Transfers to and from Levels 1, 2 and 3 are recognized at the end of the reporting period. There were no transfers between levels for the three and six months ended June 30, 2018 or for the year ended December 31, 2017.

Level 1 instruments include investments in money market funds, U.S. Treasuries and U.S. government agency obligations. These instruments are valued using quoted market prices for identical unrestricted instruments in active markets. The Company defines active markets for debt instruments based on both the average daily trading volume and the number of days with trading activity. Level 2 instruments include corporate debt securities. Valuations of Level 2 instruments can be verified to quoted prices, recent trading activity for identical or similar instruments, broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. Consideration is given to the nature of the quotations (e.g., indicative or firm) and the relationship of recent market activity to the prices provided from alternative pricing sources.

Fair values of these assets are based on prices provided by independent market participants that are based on observable inputs using market-based valuation techniques. These valuation models and analytical tools use market pricing or similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company did not adjust any of the valuations received from these third parties with respect to any of its Level 1 or 2 securities for the six-month period ended June 30, 2018 or the year-ended December 31, 2017 and did not have any Level 3 financial assets or liabilities during either of these periods.

Note 5. Available-for-Sale Securities

The Company's portfolio of available-for-sale securities consists of U.S. Treasuries and high credit quality corporate debt securities. The following is a summary of the Company's available-for-sale securities at June 30, 2018:

	June 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
U.S. Treasury securities	$ 11,997,649	$ —	$ (8,064)	$ 11,989,585
Corporate debt securities	22,969,626	—	(3,275)	22,966,351
Total available-for-sale securities	$ 34,967,275	$ —	$ (11,339)	$ 34,955,936

The Company had no available-for-sale securities at December 31, 2017.

The net adjustment to unrealized holding gains (losses) on available-for-sale securities, net of tax in other comprehensive income totaled $(188) and $(11,339) for the three and six months ended June 30, 2018, and $736 and $1,090 for the three and six months ended June 30, 2017, respectively.

Contractual maturities of debt investment securities at June 30, 2018 are shown below. Expected maturities will differ from contractual maturities because the issuers of the securities may have the right to prepay obligations without prepayment penalties.

	Under 1 Year	1 to 2 Years	Total
U.S. Treasury securities	$ 11,989,585	$ —	$ 11,989,585
Corporate debt securities	22,966,351	—	22,966,351
Total available-for-sale securities	$ 34,955,936	$ —	$ 34,955,936

The following table shows the gross unrealized losses and fair values of the Company's investments that have unrealized losses, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position as of June 30, 2018:

	Under 1 Year		1 to 2 Years		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. Treasury securities	$ 11,989,585	$ (8,064)	$ —	$ —	$ 11,989,585	$ (8,064)
Corporate debt securities	2,391,305	(3,275)	—	—	2,391,305	(3,275)
Total available-for-sale securities with unrealized losses	$ 14,380,890	$ (11,339)	$ —	$ —	$ 14,380,890	$ (11,339)

For debt securities, the Company determines whether it intends to sell or if it is more likely than not that it will be required to sell impaired securities. This determination considers current and forecasted liquidity requirements, regulatory and capital requirements and securities portfolio management. For all impaired debt securities for which there was no intent or expected requirement to sell, the evaluation considers all available evidence to assess whether it is likely the amortized cost value will be recovered. The Company conducts a regular assessment of its debt securities with unrealized losses to determine whether securities have other-than-temporary impairment considering, among other factors, the nature of the securities, credit rating or financial condition of the issuer, the extent and duration of the unrealized loss, expected cash flows of underlying collateral, market conditions and whether the Company intends to sell or it is more likely than not that the Company will be required to sell the debt securities. The Company did not have any other-than-temporary impairment in its available-for-sale securities at June 30, 2018 or December 31, 2017.

Note 6. Property and Equipment

Property and equipment, net, consists of the following as of the dates indicated:

	June 30, 2018	December 31, 2017
Furniture & fixtures	$ 686,349	$ 582,007
Leasehold improvements	1,895,216	1,863,698
Equipment used in manufacturing	2,147,331	1,963,558
Equipment used in research & development	1,456,954	1,328,556
Equipment used in the field	130,552	130,552
Software	373,683	373,683
Construction in progress	158,211	255,641
	6,848,296	6,497,695
Less: accumulated depreciation and amortization	(3,959,301)	(3,192,805)
	$ 2,888,995	$ 3,304,890

Depreciation and leasehold improvement amortization expense was $422,140 and $778,344 for the three and six months ended June 30, 2018, respectively, and $291,421and $587,466 for the three and six months ended June 30, 2017, respectively.

Note 7. Accrued Liabilities

Accrued liabilities consist of the following as of the dates indicated:

	June 30, 2018	December 31, 2017
Accrued employee bonuses	$ 1,365,489	$ 3,049,109
Payroll and employee benefit accruals	623,713	369,275
Accrued professional fees	112,320	101,150
Accrued interest	107,116	45,544
Other accrued liabilities	219,138	181,708
	$ 2,427,776	$ 3,746,786

Note 8. Debt Obligations

Growth Term Loan

Total amortization expense for warrant, final fee and original issuance discounts in connection with the growth capital term loans under the Loan and Security Agreement dated August 22, 2014 between the Company and Oxford Finance, LLC and Silicon Valley Bank (the "Growth Term Loan") was $0 and $59,969 for the three and six months ended June 30, 2018, respectively, and $103,741 and $220,731 for the three and six months ended June 30, 2017, respectively, and is included in interest expense in the accompanying interim unaudited condensed statements of operations. Deferred financing cost amortization expense relating to the Growth Term Loan was $0 and $2,982 for the three and six months ended June 30, 2018, respectively, and $4,995 and $10,588 for the three and six months ended June 30, 2017, respectively, and is included in interest expense in the accompanying interim unaudited condensed statements of operations. The Company recorded $0 and $58,538 of discounts associated with the Growth Term Loan in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively.

Extinguishment of Growth Term Loan upon MidCap Credit Facility Closing

In March 2018, the Company repaid all principal and interest amounts outstanding under the Growth Term Loan in an aggregate amount equal to approximately $4.3 million, including collateral agent legal fees and prepayment fees. The repayment was funded with net proceeds from the MidCap Credit Facility (see description of the MidCap Credit Facility below). As a result of the repayment, the Company recorded a loss on extinguishment of the Growth Term Loan of $0 for the three months ended June 30, 2018 and $105,064, including remaining unamortized discounts of $67,272 and prepayment and other Growth Term Loan lender fees in the accompanying interim unaudited condensed statements of operations for the six months ended June 30, 2018. All obligations under the Growth Term Loan were terminated upon extinguishment of the Growth Term Loan.

MidCap Credit Facility

On March 26, 2018 (the "MidCap Closing Date"), the Company entered into a Credit and Security Agreement (Term Loan) (the "MidCap Term Loan") and a Credit and Security Agreement (Revolving Loan) (the "MidCap Revolving Loan" and together with the MidCap Term Loan, the "MidCap Credit Facility") with MidCap Financial Trust, as agent. MidCap Financial Trust subsequently assigned its rights and obligations as agent to MidCap Funding IV Trust.

The MidCap Term Loan provides a secured term loan facility in an aggregate principal amount of up to $20.0 million. The Company borrowed the first advance of $7.0 million ("MidCap Tranche 1") on the MidCap Closing Date. Under the terms of the MidCap Term Loan, the second advance of $13.0 million ("MidCap Tranche 2") will be available to the Company on or before September 30, 2019, subject to the Company's satisfaction of certain conditions described in the MidCap Term Loan, including (a) the Company achieving the first commercial sale of an FDA-approved diagnostic assay utilizing next generation sequencing under its Governing Agreement with QML, and (b) delivery to MidCap of subordination documents in respect of the QNAH Convertible Note (or the satisfaction of alternative arrangements as provided in the MidCap Term Loan, as described below).

MidCap Tranche 1 was used to repay in full all outstanding amounts and fees due under the Growth Term Loan. The proceeds remaining from MidCap Tranche 1 and, if borrowed, the proceeds from MidCap Tranche 2, are expected to be used for working capital and general corporate purposes.

MidCap Tranche 1, and if borrowed MidCap Tranche 2, each bear interest at a floating rate equal to 7.25% per annum, plus the greater of (i) 1.25% or (ii) one-month LIBOR. Interest on each term loan advance is due and payable monthly in arrears and was calculated at a rate of 9.340% for interest accrued as of June 30, 2018. Principal on each term loan advance is payable in 36 equal monthly

installments beginning April 1, 2020 until paid in full on March 1, 2023. Prepayments of the term loans under the MidCap Term Loan, in whole or in part, will be subject to early termination fees in an amount equal to 3.0% of principal prepaid if prepayment occurs on or prior to the first anniversary of the MidCap Closing Date, 2.0% of principal prepaid if prepayment occurs after the first anniversary of the MidCap Closing Date but on or prior to the second anniversary of the MidCap Closing Date, and 1.0% of principal prepaid if prepayment occurs after the second anniversary of the MidCap Closing Date and prior to or on the third anniversary of the MidCap Closing Date. In connection with execution of the MidCap Term Loan, the Company paid MidCap a $100,000 origination fee.

Upon termination of the MidCap Term Loan, the Company is required to pay an exit fee equal to 4.50% of the principal amount of all term loans advanced to the Company under the MidCap Term Loan.

The MidCap Term Loan also requires that the Company deliver subordination documents with respect to the QNAH Convertible Note, or that the QNAH Convertible Note otherwise be converted or prepaid, on or before June 30, 2018, and requires the Company to deposit approximately $3.3 million into an escrow account by July 15, 2018 if neither of such events occurred by such date. See Note 17 for additional discussion relating to this requirement.

The MidCap Revolving Loan provides a secured revolving credit facility in an aggregate principal amount of up to $2.0 million. The Company may request an increase in the total commitments under the MidCap Revolving Loan by up to an additional $8.0 million, subject to agent and lender approval and the satisfaction of certain conditions. Availability of the revolving credit facility under the MidCap Revolving Loan will be based upon a borrowing base formula and periodic borrowing base certifications valuing certain of the Company's accounts receivable and inventory, as reduced by certain reserves, if any. Further, although the revolving credit facility was made available following establishment of required lockbox arrangements by the Company in June 2018, there were no amounts outstanding under the MidCap Revolving Loan as of June 30, 2018. The proceeds of any loans under the MidCap Revolving Loan may be used for working capital and general corporate purposes.

Loans under the MidCap Revolving Loan accrue interest at a floating rate equal to 4.25% per annum, plus the greater of (i) 1.25% or (ii) one-month LIBOR. Accrued interest on the revolving loans will be paid monthly and revolving loans may be borrowed, repaid and re-borrowed until March 1, 2023, when all outstanding amounts must be repaid. Subject to certain exceptions, termination or permanent reductions of the revolving loan commitment under the MidCap Revolving Loan will be subject to termination fees in an amount equal to 3.0% of the commitment amount terminated or reduced if such termination or reduction occurs on or prior to the first anniversary of the MidCap Closing Date, 2.0% of the commitment amount terminated or reduced if such termination or reduction occurs after the first anniversary of the MidCap Closing Date but on or prior to the second anniversary of the MidCap Closing Date, and 1.0% of the commitment amount terminated or reduced if such termination or reduction occurs after the second anniversary of the MidCap Closing Date and prior to or on the third anniversary of the MidCap Closing Date.

In connection with the MidCap Revolving Loan, the Company is required to pay customary fees, including an origination fee of 0.50% of the original commitment amount at closing (and an equivalent origination fee with respect to any increased commitments at the time of the applicable increase), a monthly unused line fee of 0.50% per annum based upon the average daily unused portion of the revolving credit facility and a monthly collateral management fee of 0.50% per annum based upon the average daily used portion of the revolving credit facility. The Company is also required to maintain a minimum drawn balance of not less 20% of availability under the revolving line. If the Company does not maintain such minimum drawn balance, it is required to pay monthly interest and fees as if an amount equal to 20% of availability had been drawn down under the revolving line.

The Company's obligations under the MidCap Credit Facility are secured by a security interest in substantially all of its assets, excluding intellectual property (which is subject to a negative pledge). Additionally, the Company's future subsidiaries, if any, may be required to become co-borrowers or guarantors under the MidCap Credit Facility.

The MidCap Credit Facility contains customary affirmative covenants and customary negative covenants limiting the Company's ability and the ability of the Company's subsidiaries, if any, to, among other things, dispose of assets, undergo a change in control, merge or consolidate, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. Commencing with the calendar quarter ending on the later of (a) June 30, 2019 and (b) the last day of the calendar quarter in which MidCap Tranche 2 is funded, the Company must also comply with a financial covenant relating to trailing twelve-month minimum Net Revenue requirements (as defined in the MidCap Credit Facility), tested on a quarterly basis.

The MidCap Credit Facility also contains customary events of default relating to, among other things, payment defaults, breaches of covenants, a material adverse change, delisting of the Company's common stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments, and inaccuracies of representations and warranties. Upon an event of default, agent and the lenders may declare all or a portion of the Company's outstanding obligations to be immediately due and payable and exercise other rights and remedies provided for under the agreement. During the existence of an event of default, interest on the obligations could be increased by 3.0%.

The Company granted the lender ten-year warrants to purchase 18,123 shares of the Company's common stock at $7.73 per share as a result of Tranche 1. Upon drawdown of Tranche 2, the Company will issue additional ten-year warrants to purchase shares of the Company's common stock in an aggregate amount equal to 2.0% of the amount drawn, divided by the exercise price per share for that tranche (defined as 1.5 times the volume-weighted average closing price of the Company's common stock for the ten business days immediately preceding the business day before the issue date). The fair value of the warrants on the date of issuance was approximately $74,000, determined using the Black-Scholes option-pricing model, and was recorded as a discount to the MidCap Term Loan.

The Company recognized approximately $729,269 of debt discount associated with the MidCap Term Loan, resulting from fees and debt issuance costs, in the accompanying interim unaudited condensed balance sheets as of June 30, 2018. Amortization of the debt discount associated with the MidCap Term Loan was approximately $41,155 and $43,856 for the three and six months ended June 30, 2018 and was included in interest expense in the accompanying interim unaudited condensed statements of operations. Costs incurred in connection with the issuance of the Midcap Revolving Loan of $75,184 are presented as MidCap revolving loan costs in the accompanying interim unaudited condensed balance sheets as of June 30, 2018. Amortization of deferred MidCap revolving loan costs was $4,013 and $4,236 for the three and six months ended June 30, 2018, respectively, and are included in interest expense in the accompanying interim unaudited condensed statements of operations.

Other Debt Obligations to Related Parties

Refer to Note 16 below for discussion of debt obligation to related parties.

Note 9. Revenue from Contracts with Customers

Revenue from contracts with customers is recognized when, or as, the Company satisfies its performance obligations by delivering the promised goods or service deliverables to the customers. A good or service deliverable is transferred to a customer when, or as, the customer obtains control of that good or service deliverable. A performance obligation may be satisfied over time or at a point in time. Revenue from a performance obligation satisfied over time is recognized by measuring the Company's progress in satisfying the performance obligation in a manner that depicts the transfer of the goods or services to the customer. Revenue from a performance obligation satisfied at a point in time is recognized at the point in time that the Company determines the customer obtains control over the promised good or service deliverable. The amount of revenue recognized reflects the consideration the Company expects to be entitled to in exchange for those promised goods or services (*i.e.*, the "transaction price"). In determining the transaction price, the Company considers multiple factors, including the effects of variable consideration. Variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. In determining when to include variable consideration in the transaction price, the Company considers the range of possible outcomes, the predictive value of its past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of the Company's influence, such as the judgment and actions of third parties.

Product and Product-related Services Revenue

The Company had product and product-related services revenue consisting of revenue from the sale of instruments and consumables and the use of the HTG EdgeSeq proprietary technology to process samples and design custom RUO assays for the three and six months ended June 30, 2018 and 2017 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product revenue:				
Instruments	$ 273,509	$ 148,479	$ 284,867	$ 171,058
Consumables	593,100	258,698	845,112	777,263
Total product revenue	866,609	407,177	1,129,979	948,321
Product-related services revenue:				
Custom RUO assay development	176,697	304,661	303,724	345,948
Sample processing	980,006	746,507	2,323,155	1,535,245
Total product-related services revenue	1,156,703	1,051,168	2,626,879	1,881,193
Total product and product-related services revenue	$ 2,023,312	$ 1,458,345	$ 3,756,858	$ 2,829,514

Because the Company's agreements for product and product-related services revenue have an expected duration of one year or less, the Company has elected the practical expedient in ASC 606-10-50-14(a) to not disclose information about its remaining performance obligations.

Sale of Instruments and Consumables

The delivery of each instrument and related installation and calibration are considered to be a single performance obligation, as the HTG EdgeSeq instrument must be professionally installed and calibrated prior to use. Instrument product revenue is generally recognized upon installation and calibration of the instrument by field service engineers, which represents the point at which the customer has the ability to use the instrument and has accepted the asset. Installation generally occurs within one month of instrument shipment.

The delivery of each consumable is a separate performance obligation. Consumables revenue is recognized upon transfer of control, which represents the point when the customer has legal title and the significant risks of ownership of the asset. The Company's standard terms and conditions provide that no right of return exists for instruments and consumables, unless replacement is necessary due to delivery of defective or damaged product. Customer payment terms vary but are typically between 30 and 90 days of revenue being earned from shipment or delivery, as applicable.

Shipping and handling fees charged to the Company's customers for instruments and consumables shipped are included in the accompanying interim unaudited condensed statements of operations as part of product and product-related services revenue. Shipping and handling costs for sold products shipped to the Company's customers are included in the accompanying interim unaudited condensed statements of operations as part of cost of revenue.

For sales of consumables in the United States, standard delivery terms are FOB shipping point, unless otherwise specified in the customer contract, reflecting transfer of control to the customer upon shipment. The Company has elected the practical expedient to account for shipping and handling as activities to fulfill the promise to transfer the consumables.

The Company provides instruments to certain customers under reagent rental agreements. Under these agreements, the Company installs instruments in the customer's facility without a fee and the customer agrees to purchase consumable products at a stated price over the term of the agreement; in some instances, the agreements do not contain a minimum purchase requirement. Terms range from several months to multiple years and may automatically renew in several month or multiple year increments unless either party notifies the other in advance that the agreement will not renew. The Company measures progress toward complete satisfaction of its performance obligation to provide the instrument and deliver the consumables using an output method based on the number of consumables delivered in relation to the total consumables to be provided under the reagent rental agreement. This is considered to be representative of the delivery of outputs under the arrangement and the best measure of progress because the customer benefits from the instrument only in conjunction with the consumables. The Company expects to recover the cost of the instrument under the agreement through the fees charged for consumables, to the extent sold, over the term of the agreement.

In reagent rental agreements, the Company retains title to the instrument and title is transferred to the customer at no additional charge at the conclusion of the initial arrangement. The cost of the instrument is amortized on a straight-line basis over the term of the arrangement, unless there is no minimum consumable product purchase in which case the instrument would be expensed as cost of revenue upon installation. Cost to maintain the instrument while title remains with the Company is charged to selling, general and administrative expense as incurred.

Sample Processing

The Company also provides sample processing services and molecular profiling of retrospective cohorts for its customers through its VERI/O laboratory, whereby the customer provides samples to be processed using HTG EdgeSeq technology specified in the order. Customers are charged a per sample fee for sample processing services which is recognized as revenue upon delivery of a data file to the customer showing the results of testing and completing delivery of the agreed upon service. This is when the customer can use and benefit from the results of testing and the Company has the present right to payment.

Custom RUO Assay Design and Related Agreements

The Company enters into custom RUO assay design agreements that may generate up-front fees and subsequent payments that might be earned upon completion of design process phases. The Company measures progress toward complete satisfaction of its performance obligation to perform custom RUO assay design using an output method based on the costs incurred to date compared to total expected costs, as this is considered to be representative of the delivery of outputs under the arrangements and the best measure of progress. However, because in most instances the assay development fees are contingent upon completion of each phase of the design project and the decision of the customer to proceed to the next phase, the amount to be included in the transaction price and recognized as revenue is limited to that which the customer is contractually obligated to pay upon completion of that phase, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Changes in estimates of

total expected costs are accounted for prospectively as a change in estimate. From period to period, custom RUO assay design service revenue can fluctuate substantially based on the completion of design-related phases.

Bristol-Myers Squibb Company Agreement

In May 2016, the Company entered into a Collaboration Agreement with Bristol-Myers Squibb Company ("BMS") for the design of at least two custom RUO assays for BMS based on the Company's HTG EdgeSeq technology. Following design of each assay, at BMS's request, the Company may also perform sample processing services using such custom RUO assay(s) and/or supply the custom RUO assay(s) to BMS or its third-party subcontractors. Additional custom RUO assay design services related to immuno-oncology research may be undertaken pursuant to the agreement in accordance with a mutually acceptable work plan, which is incorporated by written amendment.

BMS paid an initial non-refundable, non-creditable program set-up fee upon initiation of the agreement, and has agreed to pay an annual non-refundable, non-creditable project management fee in quarterly installments as well as a custom RUO assay design fee for each assay designed.

In January 2018, the Company and BMS amended the terms of the parties' Collaboration Agreement to increase the development fee payable by BMS to the Company for each of the two initial custom RUO assays contemplated by the agreement from a low six-figure range to a mid six-figure dollar amount, and to modify certain custom RUO assay design requirements. With the amendment of the agreement, the Company estimates that the first custom research assay design project initiated under this agreement will be completed before December 31, 2018. See contract liabilities note below for further discussion of the impact of this modification on the Collaboration Agreement.

The Company has determined that the agreement does not meet the definition of a collaborative arrangement and that BMS meets the definition of a customer under ASC 606. Additionally, each SOW issued for an RUO custom assay design project contemplated by the agreement represents a single performance obligation to provide custom RUO assay design services. In addition, if BMS should opt to purchase completed custom RUO assay kits or sample processing services, these add-on services would not be combined with the custom RUO assay design performance obligations. Instead, these would be additional contracts with BMS accounted for using the Company's policy for consumable product and sample processing revenue recognition under ASC 606 at the time such request is made.

The initial set-up fee is a fixed fee and is included in the transaction price. The RUO custom assay design fee relating to each assay design project contemplated under the agreement represents variable consideration because the assay design fees are contingent upon completion of each phase of the design project and the decision of BMS to proceed to the next phase. The quarterly project management fees represent variable consideration because they are payable by BMS through the completion of the second of the two custom assay design projects or termination of the agreement. The Company uses the most likely amount method to measure the variable consideration for its RUO custom assay design fees, which are constrained and excluded from the transaction price until BMS is contractually obligated to pay the fees upon completion of that phase, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

The initial set-up fee is included in the transaction price and is being recognized as revenue using an output method that measures progress based on the specific output provided to BMS, such as an internal document generated or conclusion reached.

The agreement will expire on May 11, 2019 or, if a project is then ongoing, the date of delivery of the final report for such project. Either party may terminate the agreement upon the other party's material breach or default in the performance of a material obligation under the agreement or if certain warranties or representations are untrue in any material respect (each a "BCA Default") and such BCA Default remains uncured for 60 days or such longer period if the BCA Default cannot be cured within 60 days. BMS may terminate a project upon 90 days' prior written notice to the Company.

For the three and six months ended June 30, 2018, $70,919 and $132,224, respectively, was recognized under the agreement as product and product-related services revenue in the accompanying interim unaudited condensed statements of operations, compared to $31,250 and $62,500 for the three and six months ended June 30, 2017, respectively. Contract liabilities relating to this agreement of $90,382 and $160,106 were included in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively. As of June 30, 2018, the aggregate amount of the transaction price allocated to the partially unsatisfied performance obligation was $50,000. The Company expects to recognize the revenue for this amount between July 2018 and December 2019 using the same output method that the Company uses for its custom RUO assay design performance obligations with BMS.

Collaborative Development Services Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaborative development services	$ 2,887,454	$ 302,411	$ 5,312,560	$ 302,411

See Note 16 for discussion of collaborative development services contracts with related parties. There was no collaborative development services revenue generated from the Company's companion diagnostic development services agreements with non-related party customers for the three and six months ended June 30, 2018. This includes the Company's Master CDx Agreement with Merck KGaA, Darmstadt, Germany, for which there have been no significant modifications or financial events relating to the agreement since the disclosures made by the Company in its Annual Report on Form 10-K, filed with the SEC on March 23, 2018.

The Company earned the first milestone-based payment under the Master CDx Agreement in the second quarter of 2017, resulting in recognition of $25,000 of collaborative development services revenue for the three and six months ended June 30, 2017.

Contract Liabilities

The Company receives up-front payments from customers for custom RUO assay design services, and occasionally for sample processing services. Payments for instrument extended warranty contracts are made in advance as are payments for certain agreed-upon capital purchases required for collaborative development service projects. The Company recognizes such up-front payments as a contract liability. The contract liability is subsequently reduced at the point in time that the data file is delivered for sample processing services or as the Company satisfies its performance obligations over time for RUO assay design, collaborative development and extended warranty services. Contract liabilities of $448,717 and $837,885 were included in contract liabilities – current and other non-current liabilities in the accompanying unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively.

Changes in the Company's contract liability were as follows as of the date indicated:

	Product Revenue	Custom RUO Assay Design	Sample Processing	Collaborative Development Services	Total Contract Liability
Balance at January 1, 2018	$ 39,426	$ 197,606	$ 354,911	$ 245,942	$ 837,885
Deferral of revenue	90,353	231,500	72,540	70,918	465,311
Recognition of deferred revenue	(91,797)	(301,224)	(262,723)	(198,735)	(854,479)
Balance at June 30, 2018	$ 37,982	$ 127,882	$ 164,728	$ 118,125	$ 448,717

Included in recognition of deferred revenue for the three and six months ended June 30, 2018 was a cumulative catch up adjustment of $0 and $30,055, respectively, to custom RUO assay design revenue relating to the January 2018 modification of the Company's Collaboration Agreement with BMS for custom RUO assay design discussed above.

Note 10. Other Agreements

NuvoGen Obligation

Pursuant to the Company's asset purchase agreement with NuvoGen Research, LLC ("NuvoGen"), as amended, the Company is obligated to pay NuvoGen the greater of $400,000 or 6% of annual revenue until the obligation is paid in full. Although an amendment to the agreement allowed for deferral of any revenue-based payments through December 31, 2017, no revenue-based payments were deferred. In addition to fixed quarterly payments of $100,000, revenue-based payments of $194,646 and $85,574 were payable as of June 30, 2018 and December 31, 2017, respectively. There have been no significant modifications to the terms and conditions of the Company's NuvoGen obligation since the disclosures made in the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2018.

The minimum remaining payments due to NuvoGen at June 30, 2018, including $194,646 of additional revenue-based payments payable as of June 30, 2018, are as follows for each fiscal year, although actual payments could be significantly more than provided in the table, to the extent that 6% of the Company's annual revenue exceeds $400,000:

2018	$ 394,646
2019	400,000
2020	400,000
2021	400,000
2022	400,000
2023 and beyond	5,469,004
Total NuvoGen obligation payments	7,463,650
Plus interest accretion	112,606
Total NuvoGen obligation, net	$ 7,576,256

Illumina, Inc. Agreement

In June 2017, the Company entered into an Amended and Restated Development and Component Supply Agreement with Illumina, Inc. ("Illumina"), effective May 31, 2017 ("Restated Agreement"), which amended and restated the parties' IVD Test Development and Component Supply Agreement entered into in October 2014 ("Original Agreement"). The Restated Agreement provides for the development and worldwide commercialization by the Company of nuclease-protection-based RNA or DNA profiling tests ("IVD test kits") for use with Illumina's MiSeqDx sequencer in the field of diagnostic oncology testing in humans ("Field").

The Company submitted a development plan for an IVD test kit to Illumina, resulting in a required payment to Illumina of $50,000 for the three and six months ended June 30, 2017. There have been no financial events relating to the Restated Agreement for the three and six months ended June 30, 2018.

Other Development Agreements

There have been no significant modifications or financial events relating to the development agreements entered into by the Company in prior periods with Invetech PTY Ltd. since the disclosures made by the Company in its Annual Report on Form 10-K, filed with the SEC on March 23, 2018.

Note 11. Net Loss Per Share

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per common share is computed similar to basic loss per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table provides the numerator and denominator used in computing basic and diluted net loss per share for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$ (4,102,729)	$ (5,840,902)	$ (9,482,676)	$ (11,657,176)
Denominator:				
Weighted-average shares outstanding-basic and diluted	28,375,379	9,769,322	26,549,895	8,875,177
Net loss per share, basic and diluted	$ (0.14)	$ (0.60)	$ (0.36)	$ (1.31)

The following outstanding securities were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Six Months Ended June 30,	
	2018	2017
Options to purchase common stock	1,693,575	1,436,978
Common stock warrants	237,846	219,723
Restricted stock units	26,666	208,999
QNAH convertible note	766,381	—

Note 12. Warrants

In connection with certain of its redeemable convertible preferred stock issuances, convertible debt financings and other financing arrangements, the Company has issued warrants for shares of its common stock and various issues of its redeemable convertible preferred stock which have since been converted to common stock warrants. There have been no significant modifications or financial events relating to the warrants that were issued prior to December 31, 2017 since the disclosures made by the Company in its Annual Report on Form 10-K, filed with the SEC on March 23, 2018.

In March 2018, in connection with the Company's entry into the MidCap Credit Facility (see Note 8), the Company issued warrants to purchase an aggregate of 18,123 shares of the Company's common stock, at an exercise price equal to $7.73 per share as a result of the funding of MidCap Tranche 1. The warrants are immediately exercisable and expire on the earlier to occur of the tenth anniversary of the respective issue date or, in certain circumstances, the closing of a merger, sale or other consolidation transaction in which the consideration is cash, stock of a publicly traded acquirer, or a combination thereof.

The following table shows the common stock warrants outstanding as of June 30, 2018:

Shares of Common Stock Underlying Warrants	Exercise Price/Share	Expiration Date
28,713	23.51	2024
144,772	14.00	2022
931	6.45	2019
45,307	2.76	2026
18,123	7.73	2028

Note 13. Stockholders' Deficit

Public Offerings

ATM Offering

In April 2017, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), as sales agent, pursuant to which the Company had the right to offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value $0.001 per share, by any method deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended (the "ATM Offering"). In April 2017, the Company also filed a prospectus supplement (File No. 333-216977) with the SEC relating to the offer and sale of up to $20.0 million of common stock in the ATM Offering. In June 2017, the Company filed a first amendment to the prospectus supplement with the SEC to increase the amount of common stock that could be offered and sold in the ATM Offering under the Sales Agreement to $40.0 million in the aggregate, inclusive of the common stock previously sold in the ATM Offering prior to the date of the first amendment. In January 2018, the Company filed a second amendment to the prospectus supplement with the SEC to decrease the amount of common stock that could be offered and sold in the ATM Offering under the Sales Agreement to $23.0 million in the aggregate, inclusive of the common stock sold in the ATM Offering prior to the date of the second amendment. In February 2018, the Company and Cantor mutually agreed to terminate the Sales Agreement.

Prior to termination of the Sales Agreement, the Company sold 5,733,314 shares of common stock under the ATM Offering at then-market prices for total gross proceeds of approximately $21.1 million, including 0.3 million shares of common stock sold for gross proceeds of $0.6 million during the first quarter ended March 31, 2018. After $0.6 million of sales commissions and $0.2 million of other offering expenses paid by the Company in connection with the ATM Offering, the Company's aggregate net proceeds from the ATM Offering were approximately $20.2 million. Sales commissions and offering expenses have been recorded as a reduction of proceeds received in arriving at the amount recorded in additional paid-in capital in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017.

Underwritten Public Offering

In January 2018, the Company completed an underwritten public offering of 13,915,000 shares of its common stock at a price of $2.90 per share, including 1,815,000 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company sold its common stock through an underwriting agreement with Leerink Partners LLC and Cantor as representatives of the underwriters for the offering. The aggregate net proceeds to the Company from the offering were approximately $37.7 million, after deducting the underwriting discounts and commissions and offering expenses.

Stock-based Compensation

A summary of the Company's stock option activity for the six months ended June 30, 2018 is as follows:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at December 31, 2017	1,517,771	$ 2.97	7.5	$ 67,242
Granted	272,500	3.38		
Exercised	(33,651)	2.07		$ 51,816
Forfeited	(23,190)	3.60		
Expired/Cancelled	(39,855)	6.83		
Balance at June 30, 2018	1,693,575	$ 2.95	7.4	$ 1,262,339
Exercisable at June 30, 2018	1,163,017	$ 2.89	6.6	$ 1,061,522

As of June 30, 2018, there was total unrecognized compensation expense of $937,490 related to unvested stock options, which the Company expects to recognize over a weighted-average period of approximately 2.98 years.

In June 2018, in connection with the retirement of two employees, the vesting of stock options covering 46,613 shares of common stock was accelerated, and the post-termination exercise period for the employees' options were extended to a one year period from the termination date. As a result of this modification, the Company recorded incremental stock-based compensation expense of approximately $79,400 for the three and six months ended June 30, 2018.

A summary of restricted stock unit ("RSU") activity for the six months ended June 30, 2018 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2017	26,666	$ 2.78
Granted	269,551	3.82
Vested	(269,551)	3.76
Balance at June 30, 2018	26,666	$ 3.34

Unrecognized compensation expense related to the remaining unvested RSUs was $70,313 at June 30, 2018, which the Company expects to recognize over a weighted-average remaining service period of 2.56 years.

Stock-based compensation expense recorded in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018 and 2017 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Selling, general and administrative	$ 173,666	$ 294,591	$ 1,275,658	$ 574,174
Research and development	49,189	93,103	80,098	181,464
Cost of revenue	19,065	30,243	29,622	58,945
	$ 241,920	$ 417,937	$ 1,385,378	$ 814,583

Stock-based compensation expense for the three and six months ended June 30, 2018 included $1.0 million of selling, general and administrative compensation expense relating to the issuance of 259,551 shares under restricted stock units ("RSUs") granted to the Company's executive officers in January 2018 at a grant date fair value of $3.84 per share. The RSUs vested in full on January 29, 2018.

Note 14. Commitments and Contingencies

Compensation Agreements

In September 2017, the Company entered into an arrangement with certain of its non-executive officer employees to provide for retention bonus payments to those eligible employees providing continuing service to the Company through July 31, 2018 and December 31, 2018, with one half of the retention bonus commitment payable at each of these dates. Compensation expense of $244,588 and $472,813 has been included in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively. Retention bonus accrual is included in accrued liabilities in the accompanying interim unaudited condensed balance sheets as of June 30, 2018. The remaining retention bonuses will be accrued on a straight-line basis through December 31, 2018. No forfeiture rate has been estimated. Forfeitures will be recognized as they occur.

Legal Matters

The Company's industry is characterized by frequent claims and litigation, including claims regarding intellectual property and product liability. As a result, the Company may be subject to various legal proceedings from time to time. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. Any current litigation is considered immaterial and counter claims have been assessed as remote.

Leases

The Company leases office and laboratory space in Tucson, Arizona under two non-cancelable operating leases. There have been no changes to the Company's office and laboratory space leases since the disclosures made by the Company in its Annual Report on Form 10-K, filed with the SEC on March 23, 2018.

The Company's remaining minimum real estate lease payments before common area maintenance charges for each fiscal year as of June 30, 2018 are as follows:

2018	$ 256,166
2019	514,977
2020	517,457
2021	43,139
	$ 1,331,739

As of June 30, 2018, the Company also has remaining capital lease commitments consisting of approximately $88,700 for computer equipment varying in length from 36 to 48 months that has not been included in the minimum lease payments schedule above.

Product Warranty

The following is a summary of the Company's general product warranty reserve for the periods indicated:

	Six Months Ended June 30,	
	2018	2017
Beginning balance	$ 37,156	$ 50,426
Cost of warranty claims	(2,358)	(4,296)
Increase (decrease) in warranty reserve	24,857	(14,817)
Ending balance	$ 59,655	$ 31,313

Warranty reserve is included in accrued liabilities in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017. Expense relating to the recording of this reserve is recorded in cost of revenue within the accompanying interim unaudited condensed statements of operations.

Note 15. Income Taxes

The Company provides for income taxes based upon management's estimate of taxable income or loss for each respective period. The Company recognizes an asset or liability for the deferred tax consequences of temporary differences between the tax bases of assets and liabilities and their reported amounts in the financial statements. These temporary differences would result in deductible or taxable amounts in future years, when the reported amounts of the assets are recovered or liabilities are settled, respectively.

In each period since inception, the Company has recorded a valuation allowance for the full amount of its net deferred tax assets, as it is not more likely than not that these will be realized. As a result, the Company has not recorded any federal or state income tax benefit in the accompanying interim unaudited condensed statements of operations; however, state income tax expense has been recorded for state minimum taxes.

The Company periodically reviews its filing positions for all open tax years in all U.S. federal, state and international jurisdictions where the Company is or might be required to file tax returns or other required reports.

The Company applies a two-step approach to recognizing and measuring uncertain tax positions. The Company evaluates the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained in a court of last resort. The term "more likely than not" means a likelihood of more than 50 percent. Otherwise, the Company may not recognize any of the potential tax benefit associated with the position. The Company recognizes a benefit for a tax position that meets the more likely than not criterion at the largest amount of tax benefit that is greater than 50 percent likely of being realized upon its effective resolution. Unrecognized tax benefits involve management's judgment regarding the likelihood of the benefit being sustained. The final resolution of uncertain tax positions could result in adjustments to recorded amounts and may affect the Company's results of operations, financial position and cash flows. The Company has not identified any uncertain tax positions at June 30, 2018 or December 31, 2017.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties at June 30, 2018 and December 31, 2017, respectively, and has not recognized interest or penalties of significance during the three months ended June 30, 2018 and 2017, respectively, since there are no material unrecognized tax benefits. The Company has not made or had payments due for income taxes for the periods ended June 30, 2018 or December 31, 2017, other than state minimum taxes. Management believes no material change to the amount of unrecognized tax benefits will occur within the next 12 months.

The Company has established a valuation allowance against the entire net deferred tax asset. A preliminary analysis of past and subsequent equity offerings by the Company, and other transactions that have an impact on the Company's ownership structure, concluded that the Company may have experienced one or more ownership changes under Sections 382 and 383 of the Internal Revenue Code or IRC. Provisions of the IRC place special limitations on the usage of net operating losses and credits following an ownership change. Such limitations may limit or eliminate the potential future tax benefit to be realized by the Company from its accumulated net operating losses and research and development credits.

On December 22, 2017, federal tax legislation commonly referred to as the Tax Cuts and Jobs Act ("Tax Act") was signed into law. The Tax Act, among other changes, reduced the U.S. federal corporate tax rate from 35% to 21%, effective January 1, 2018. Consequently, for the year ended December 31, 2017, the Company recorded a decrease related to deferred tax assets of $16,232,211, exclusive of the corresponding change in the valuation allowance. Due to the full valuation allowance on the deferred tax assets, there was no net adjustment to the deferred tax expense or benefit due to the reduction of the corporate tax rate. Other changes effective January 1, 2018 include, but are not limited to, creating a new limitation on deductible interest expense, eliminating the corporate alternative minimum tax, modifying the rules related to uses and limitations of net operating loss carryforwards generated in tax years ending after December 31, 2017, limiting the deductibility of certain executive compensation, and changing the rules pertaining to the taxation of profits earned abroad. The Company expects to be subject to the new limitation on deductible interest expense in 2018; however, the disallowed interest may be carried forward indefinitely. The Company's net operating losses generated in 2018 and thereafter, if any, will be subject to a new indefinite carryforward period; however, utilization of these net operating losses will be limited to 80% of taxable income in the year utilized. Net operating loss carryforwards existing as of December 31, 2017 will not be subject to this new limitation; however, those carryforwards will remain subject to the 20-year expiration period.

Note 16. Related Party Transactions

Master Assay Development, Commercialization and Manufacturing Agreement

In November 2016, the Company entered into the Governing Agreement, which creates the framework for QML and the Company to combine their technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays. Under the Governing Agreement, the parties jointly seek companion diagnostic programs with biopharmaceutical companies, QML enters into sponsor project agreements with interested biopharmaceutical companies for specified projects, and QML and the Company enter into statements of work (each, an "SOW"), which set forth the rights and obligations of QML and the Company with respect to each project. There have been no significant modifications or financial events relating to the Governing Agreement since the disclosures made by the Company in its

Annual Report on Form 10-K, filed with the SEC on March 23, 2018, other than with regard to the initiation of new SOWs under the Governing Agreement as discussed below.

The Company has determined that SOW One, SOW Two and SOW Three (each defined below) are collaborative arrangements and that QML meets the definition of a customer under ASC 606. Additionally, each SOW is a separate contract with a single performance obligation to provide development services. Under each SOW, QML pays the Company a monthly fee for development work performed by the Company and its subcontractors (collectively, the "Monthly Fee"). The Monthly Fee is based on the employee and materials costs incurred during the month, which is subject to significant variability from period to period and unknown until the costs are incurred. Therefore, the Monthly Fee, which is based on use of hours and costs as a measure of progress, is included in the transaction price and recognized as revenue over time when the costs are incurred and the Monthly Fee is billed to QML. It is at this time that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company and QML also will share any net profits resulting from performance of the development work as determined pursuant to the Governing Agreement. Such profit sharing payment(s) is deemed to be variable consideration using the expected value method and is included in the transaction price upon completion of the respective SOW deliverables, acceptance of corresponding deliverables, and the mutual agreement by QML and the Company on the calculation of net profit, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

Because each SOW has an expected duration of one year or less, the Company has elected the practical expedient in ASC 606-10-50-14(a) to not disclose information about its remaining performance obligations for each SOW.

Statement of Work No. One

In June 2017, the Company and QML entered into the first statement of work under the Governing Agreement, which has been twice amended in December 2017 and March 2018 (collectively, "SOW One"). SOW One addressed the activities of the Company and QML in support of the development and potential commercialization of a next generation sequencing-based companion diagnostic assay that was the subject of a sponsor project agreement between QML and a biopharmaceutical company ("Pharma One"). In May 2018, SOW One was terminated by QML as a result of Pharma One's termination of the development project. The Company has discontinued development activities related to the project following wind down activities completed in the second quarter of 2018.

Revenue of $1,078,418 and $2,397,136, including SOW One Monthly Fees and $0 and $99,394 of SOW One profit sharing payments has been included in collaborative development services revenue in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively, compared to $277,400, including only SOW One Monthly Fees, for both the three and six months ended June 30, 2017. Accounts receivable relating to SOW One of $429,019 and $2,429,152 remained in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively. Costs relating to development activities conducted by the Company pursuant to SOW One of $669,994 and $1,716,115 have been included in research and development expense in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively, compared to $222,200 for both the three and six months ended June 30, 2017.

Statement of Work No. Two

In October 2017, the Company and QML entered into the second statement of work under the Governing Agreement ("SOW Two"). SOW Two was made effective as of June 2, 2017 ("Onset Date"). SOW Two addresses development activities conducted by the Company and QML since the Onset Date and those expected to be further conducted by parties in connection with a sponsor project agreement, dated June 2, 2017, between QML and BMS (the "BMS/QML SPA"). See Note 17 for further discussion of SOW Two.

Revenue of $869,827 and $1,480,818, including SOW Two Monthly Fees and $0 and $386,369 of SOW Two profit sharing payments, have been included in collaborative development services revenue in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively. Accounts receivable relating to SOW Two of $729,448 and $1,796,157 remained in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively. Costs relating to development activities conducted by the Company pursuant to SOW Two of $420,876 and $764,142 have been included in research and development expense in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively. No costs or revenue relating to SOW Two were included in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2017 as SOW Two was not established until October 2017.

Statement of Work No. Three

In January 2018, the Company and QML entered into a third statement of work ("SOW Three") under the Governing Agreement. SOW Three relates to development activities for a next generation sequencing-based clinical-trial assay ("SOW Three Project") in connection with a sponsor project agreement between QML and a pharmaceutical company ("Pharma Three"). If successfully

completed, the SOW Three Project is expected to lead to subsequent assay development activities and the potential commercialization of a companion diagnostic assay for a corresponding Pharma Three drug.

Under the terms of SOW Three, the Company has agreed to assign its rights in certain SOW Three Project-related intellectual property ("Project IP") predominantly related to Pharma Three's drug candidate(s) to QML for ultimate assignment to Pharma Three in accordance with the sponsor project agreement between QML and Pharma Three. Improvements to the background intellectual property of the Company, QML and Pharma Three generally will be owned solely by the respective party. Otherwise, Project IP will be jointly owned among the Company, QML and Pharma Three.

SOW Three expires upon completion of the SOW Three Project and receipt by the Company of all amounts due for such work. QML will pay the Company for the initial phase development services performed for SOW Three. In addition, the Company and QML will share in any net profits (as determined under the Governing Agreement) generated during the initial phase work on an approximately quarterly basis throughout the term of SOW Three.

Revenue of $939,209 and $1,434,606, including SOW Three Monthly Fees and $0 and $146,491, respectively, relating to SOW Three profit sharing payments, have been included in collaborative development services revenue in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively. Accounts receivable relating to SOW Three of $879,526 and $0 remained in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively. Costs relating to development activities conducted by the Company pursuant to SOW Three of $627,709 and $854,564 have been included in research and development expense in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2018, respectively. No costs or revenue relating to SOW Three were included in the accompanying interim unaudited condensed statements of operations for the three and six months ended June 30, 2017 as SOW Three was not established until January 2018.

QNAH Convertible Note Agreement

In October 2017, the Company issued a subordinated convertible promissory note to QNAH in the principal amount of $3.0 million against receipt of cash proceeds equal to such principal amount. There have been no significant modifications or financial events relating to QNAH Convertible Note since disclosures made by the Company in its Annual Report on Form 10-K, filed with the SEC on March 23, 2018 other than the initiation of an escrow account relating to this note in July 2018 (see Note 17).

The Company has recognized $32,513 and $39,240 of unamortized deferred financing costs incurred in connection with the issuance of the note under the QNAH Convertible Note in the accompanying interim unaudited condensed balance sheets as of June 30, 2018 and December 31, 2017, respectively. Amortization of the QNAH Convertible Note deferred financing costs was $3,364 and $6,727 for the three and six months ended June 30, 2018, respectively. Interest accrued on the QNAH Convertible Note during the three and six months ended June 30, 2018 was $22,438 and $44,630, respectively. Both amounts are included in interest expense in the accompanying interim unaudited statements of operations for the three and six months ended June 30, 2018. There was no interest accrual or deferred financing cost amortization relating to the QNAH Convertible Note for the three and six months ended June 30, 2017.

Note 17. Subsequent Events

MidCap Term Loan Escrow

The MidCap Term Loan (see Note 8) required that the Company deliver subordination documents with respect to the QNAH Convertible Note, or that the QNAH Convertible Note otherwise be converted or prepaid, on or before June 30, 2018, and required the Company to deposit approximately $3.3 million into an escrow account by July 15, 2018 if neither of such events occurred by such date. As neither of these events occurred prior to June 30, 2018, the Company deposited approximately $3.3 million into an escrow account on July 11, 2018. Such escrowed funds will be released to the Company upon subsequent delivery of the requisite subordination documents or conversion of the QNAH Convertible Note. If neither delivery of the subordination documents or conversion of the QNAH Convertible Note occurs, such funds will be applied by the escrow agent to repay in full the QNAH Convertible Note at maturity (or in connection with a prepayment at the direction of the Company), subject to (i) the Company having drawn MidCap Tranche 2, (ii) the Company having unrestricted cash and cash equivalents held in a deposit or securities account subject to a control agreement in favor of the Agent in a minimum amount of $20.0 million and (iii) there being no default under the MidCap Credit Facility.

Statement of Work No. Two Amendment

On August 8, 2018, the Company and QML entered into an amendment to SOW Two (see Note 16), effective as of July 2, 2018, which relates to a project for which HTG and QML are performing collaborative development services for what is expected to be a multi-stage project leading to the potential development and commercialization of an NGS-based companion diagnostic assay in support of one or more of BMS' therapeutic development and commercialization programs. Initial-phase investigational use only ("IUO") development activities under SOW Two have been completed and the amendment of SOW Two relates to the next phase, which includes the use of the IUO assay developed in the initial-phase in a retrospective clinical trial. Successful completion of the next phase activities could lead to the use of the assay in subsequent clinical trials and potential companion diagnostic development.

The next phase activities expected to be performed by the Company and QML under the first amendment to SOW Two are expected to be completed within the third quarter of 2018. QML will pay the Company approximately $0.5 million for work to be performed under this amendment, including project management, clinical affairs support and oversight of clinical trial by the Company and its subcontractors. In addition, the Company and QML will share in any net profits (as determined under the Governing Agreement) generated by this next phase work.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our financial statements and notes thereto for the year ended December 31, 2017, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 23, 2018. This discussion and analysis contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward looking statements include, but are not limited to, statements about:

- our ability to successfully commercialize our products and services, including our HTG EdgeSeq assays and corresponding automation system;
- our ability to secure regulatory clearance or approval, domestically and internationally, for the clinical use of our products;
- our ability to develop new technologies to expand our product offerings, including direct-target sequencing for detection of mutations in genomic DNA and/or expressed RNA (such as single-point mutations and gene rearrangements, including gene fusions and insertions), and methods to detect mutation load and microsatellite instability;
- the activities anticipated to be performed by us and third parties under design and development projects and programs, and the expected benefits and outcomes of such projects and programs;
- the implementation of our business model and strategic plans for our business;
- the regulatory regime for our products, domestically and internationally;
- our strategic relationships, including with holders of intellectual property relevant to our technologies, manufacturers of next-generation sequencing ("NGS") instruments and consumables, critical component suppliers, distributors of our products, and third parties who conduct our clinical studies;
- our intellectual property position;
- our ability to comply with the restrictions of our debt facility and meet our debt obligations;
- our expectations regarding the market size and growth potential for our life sciences and diagnostic businesses;
- our expectations regarding trends in the demand for sample processing by our biopharmaceutical company customers;
- any estimates regarding future expenses, revenues, capital requirements, and stock performance; and
- our ability to sustain and manage growth, including our ability to develop new products and enter new markets.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "continue," "seek," "project," "should," "will," "would" or the negative of those terms, and similar expressions. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this filing and are subject to risks and uncertainties. We discuss many of these risks in greater detail in Part II, Item 1A - "Risk Factors" and elsewhere in this filing. You should carefully read the "Risk Factors" section of this filing to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. These statements, like all statements in this report, speak only as of their date, and 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. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Overview

We are a commercial stage company that develops and markets products and services based on a proprietary technology that facilitates the routine use of targeted molecular profiling using a small amount of biological sample. Molecular profiling is the collection of information about multiple molecular targets, such as DNA and RNA, also called biomarkers, in a biological sample. Molecular profiling information has many important applications, from basic research to molecular diagnostics in personalized medicine. Our technology can be used throughout that range of applications, which is just one of its many benefits. Our focus is on clinical applications. Our primary customers include biopharmaceutical companies, academic research centers and molecular testing laboratories.

As part of our business model, we seek to leverage key business drivers in molecular profiling, including the acceleration of precision medicine, the migration of molecular testing to NGS-based applications, the movement to smaller and less invasive biopsies, the need for greater diagnostic sensitivity, the need to conform to challenging healthcare economics and the need for automation and an easily deployable workflow. Our products include instrumentation (or platforms), consumables, including assay kits, and software analytics that, as an integrated system, automate sample processing and can quickly, robustly and simultaneously profile tens, hundreds or thousands of molecular targets from samples a fraction of the size required by many prevailing technologies. Our objective is to establish our solutions as the standard in molecular profiling, and to make their benefits accessible to all molecular labs from research to the clinic. We believe that our target customers desire high quality molecular profiling information in a multiplexed panel format from increasingly smaller and less invasive samples, with the ability to test and analyze such information locally to minimize turnaround time and cost.

In 2014, we launched our HTG EdgeSeq technology, which generates a molecular profiling library for detection of RNA using NGS. Our HTG EdgeSeq assays are automated on our HTG EdgeSeq platform. Our innovative platform and menu of molecular profiling panels is being utilized by a wide range of customers including biopharmaceutical companies, academic institutions and molecular labs to simultaneously analyze a comprehensive set of molecular information from valuable clinical samples and improve the lab's workflow efficiency. Customers can also obtain the advantages of our proprietary technologies by engaging our VERI/O laboratory for sample processing, custom assay development and other pre-clinical activity in support of companion diagnostic programs. We currently market several proprietary molecular profiling panels that address the needs of customers in translational research, biomarker development and potentially companion diagnostics. In addition, we have a focused development pipeline that includes planned panels for translational research, drug development and molecular diagnostics. Our product strategy is to develop a suite of profiling panels with initial focus in immuno-oncology and next generation pathology.

We have two primary sources of revenue: revenue from research use only ("RUO") profiling for biopharmaceutical companies, academic research centers and molecular testing laboratories; and revenue from collaborative development services for companion diagnostic development programs for biopharmaceutical companies. RUO profiling revenue includes customer purchases of our HTG EdgeSeq instrument and related RUO assay kits, and the use of our HTG EdgeSeq instrument and RUO assay kits to process samples on the customer's behalf in our VERI/O laboratory. Collaborative development revenue relates to services performed primarily for biopharmaceutical companies pursuant to our Master Assay Development, Commercialization and Manufacturing Agreement ("Governing Agreement") with QIAGEN Manchester Limited ("QML"), a wholly owned subsidiary of QIAGEN N.V. Under the Governing Agreement, our HTG EdgeSeq proprietary technology is utilized to develop, seek regulatory approval for and commercialize companion diagnostic assays for biopharmaceutical drug candidates and corresponding therapeutics. A developing third category of revenue is the sale of our regulated diagnostic products into clinical molecular labs. Our first products are in early stage commercialization in Europe but not yet providing meaningful revenue.

We have incurred significant losses since our inception, and we have never been profitable. We incurred net losses of $4.1 million and $9.5 million for the three and six months ended June 30, 2018, respectively, and $5.8 million and $11.7 million for the three and six months ended June 30, 2017, respectively. As of June 30, 2018, we had an accumulated deficit of approximately $144.0 million. As of June 30, 2018, we had available cash and cash equivalents totaling approximately $5.8 million, investments in short-term corporate and government debt securities totaling $35.0 million and had current liabilities of approximately $4.9 million, plus an additional $16.9 million in long-term liabilities primarily attributable to our MidCap Term Loan, QNAH Convertible Note and NuvoGen obligations.

Results of Operations

Comparison of the three months ended June 30, 2018 and 2017

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2018	2017	$	%	2018	2017	$	%
Revenue:								
Product and product-related services	$ 2,023,312	$ 1,458,345	$ 564,967	39%	$ 3,756,858	$ 2,829,514	$ 927,344	33%
Collaborative development services	2,887,454	302,411	2,585,043	855%	5,312,560	302,411	5,010,149	1657%
Total revenue	4,910,766	1,760,756	3,150,010	179%	9,069,418	3,131,925	5,937,493	190%
Cost of revenue	1,450,682	1,236,904	213,778	17%	2,587,745	2,532,206	55,539	2%
Gross margin	3,460,084	523,852	2,936,232	561%	6,481,673	599,719	5,881,954	981%
Gross margin percentage	70%	30%			71%	19%		
Operating expenses:								
Selling, general and administrative	4,764,751	4,413,437	351,314	8%	10,422,583	8,651,904	1,770,679	20%
Research and development	2,758,984	1,618,889	1,140,095	70%	5,348,270	2,885,952	2,462,318	85%
Total operating expenses	7,523,735	6,032,326	1,491,409	25%	15,770,853	11,537,856	4,232,997	37%
Operating loss	(4,063,651)	(5,508,474)	1,444,823	(26%)	(9,289,180)	(10,938,137)	1,648,957	(15%)
Loss on settlement of Growth Term Loan	—	—	—	0%	(105,064)	—	(105,064)	0%
Other expense, net	(35,533)	(332,428)	296,895	(89%)	(84,887)	(718,759)	633,872	(88%)
Net loss before income taxes	$ (4,099,184)	$ (5,840,902)	$ 1,741,718	(30%)	$ (9,479,131)	$ (11,656,896)	$ 2,177,765	(19%)

Revenue

We generate revenue from two primary sources: revenue from RUO profiling for biopharmaceutical companies, academic research centers and molecular testing laboratories; and revenue from collaborative development services for biopharmaceutical companies under our clinical trial and companion diagnostic development programs.

RUO profiling is currently made available to our customers through product sales and service offerings. Customers can purchase our HTG EdgeSeq instrument and related consumables, which consist primarily of our proprietary molecular profiling panels and other assay components. Customers can also access our technology through contracted services. We perform these services using our HTG EdgeSeq instrument and RUO assay kits to process samples in our VERI/O laboratory. Our proprietary technology is also used to design custom RUO assay kits for customers who may engage us to process samples using such custom kits or to supply such custom kits for the customers' research needs and, thereby, generate future sample processing or RUO assay kit revenue.

In June 2017, we began generating revenue from collaborative development services relating to our Governing Agreement with QML with the initiation of SOW One. SOW Two was subsequently entered into in October 2017 and SOW Three was entered into in January 2018. Under these agreements, we and QML have combined our technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays in support of and in conjunction with, biopharmaceutical companies' drug development programs.

Total revenue for the three months ended June 30, 2018, increased by 179% to $4.9 million compared with $1.8 million for the three months ended June 30, 2017. Total revenue for the six months ended June 30, 2018, increased by 190% to $9.1 million compared with $3.1 million for the six months ended June 30, 2017. The increase in total revenue for the three and six months ended June 30, 2018 compared with the same period in the prior year was primarily the result of revenue generated from collaborative development services relating to our Governing Agreement with QML.

Product and product-related services revenue

Product and product-related services revenue from the sale of our HTG EdgeSeq instrument and RUO consumables and from custom RUO assay design and sample processing services performed for customers in our VERI/O laboratory using our proprietary RUO technology was $2.0 million and $3.8 million for the three and six months ended June 30, 2018, respectively, compared with $1.5 million and $2.8 million for the three and six months ended June 30, 2017, respectively, and comprised the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product revenue:				
Instruments	$ 273,509	$ 148,479	$ 284,867	$ 171,058
Consumables	593,100	258,698	845,112	777,263
Total product revenue	866,609	407,177	1,129,979	948,321
Product-related services revenue:				
Custom RUO assay development	176,697	582,072	303,724	623,359
Sample processing	980,006	469,096	2,323,155	1,257,834
Total product-related services revenue	1,156,703	1,051,168	2,626,879	1,881,193
Total product and product-related services revenue	$ 2,023,312	$ 1,458,345	$ 3,756,858	$ 2,829,514

Product revenue was $0.9 million and $1.1 million for the three and six months ended June 30, 2018, respectively, compared to $0.4 million and $0.9 million for the three and six months ended June 30, 2017, respectively, and was driven primarily from the sale of RUO assay kits in both periods. This increase in consumables sales reflects a growing customer base outside of the United States as well as targeted marketing efforts into larger U.S.-based research institutions where adoption of our technology continues to expand.

Service revenue, consisting of custom RUO assay design and sample processing using our HTG EdgeSeq instrument and consumables, was $1.2 million and $2.6 million for the three and six months ended June 30, 2018, respectively, compared to $1.1 million and $1.9 million for the three and six months ended June 30, 2017, respectively. The increase in service revenue reflects our success in growing the number of biopharmaceutical company customers who have chosen our proprietary technologies for use in their translational research and drug development programs and who prefer to gain access to our technology through purchase of our services. This increase also reflects increased consumption of our RUO assay kits used in the processing of samples in our VERI/O laboratory. We expect our revenue mix to continue to contain a higher portion of biopharmaceutical service revenue in the near term until we enter the commercial clinical diagnostic market.

Collaborative development services revenue

Collaborative development services revenue includes services performed on biopharmaceutical company clinical trial and companion diagnostic development programs using our HTG EdgeSeq proprietary technology to develop, seek regulatory approval for and potentially commercialize clinical diagnostic assays for biopharmaceutical company drug candidates and corresponding therapeutics. Collaborative development services revenue, consisting of services performed for three large biopharmaceutical companies pursuant to SOW One, SOW Two and SOW Three under our Governing Agreement with QML, was approximately $2.9 million and $5.3 million or 59% and 59% of our revenue for the three and six months ended June 30, 2018, respectively, which included approximately $485,763 in profit sharing payments. Collaborative development services revenue for both the three and six months ended June 30, 2017 was $0.3 million as SOW One was not initiated until June 2017. The amount or timing of work that we perform, the timing and number of development deliverables and the timing and amount of any profit sharing payment under these agreements is expected to continue to result in significant variability in the timing and amount of revenue recognized from one fiscal period or quarter to the next.

Cost of revenue

Cost of revenue includes the aggregate costs incurred in manufacturing, delivering, installing and servicing instruments and consumables, as well as costs incurred for services performed for customers in our VERI/O laboratory. Cost of revenue increased by $214,000, or 17%, and $55,539 or 2% for the three and six months ended June 30, 2018 compared with the three and six months ended June 30, 2017, respectively, resulting in the improvement of gross margin to 70% and 71% for the three and six months ended June 30, 2018, respectively, compared with 30% and 19% for the three and six months ended June 30, 2017, respectively. This gross margin improvement is primarily attributable to the collaborative development services performed under our Governing Agreement with QML, the revenue from which is reflected in collaborative development services revenue, and development costs from which are included in research and development expense in the accompanying interim unaudited condensed statements of operations. Additional gross margin improvement is attributable to the overall increase in product and product-related services revenue which has allowed for further absorption of our fixed operating expenses incurred in the expansion of our VERI/O laboratory staffing and buildout of our manufacturing facilities to accommodate the anticipated increase in demand for our products and services when compared to prior periods.

Selling, general and administrative expenses

Selling, general and administrative expenses were $4.8 million and $10.4 million for the three and six months ended June 30, 2018, respectively, compared to $4.4 million and $8.7 million for the three and six months ended June 30, 2017, respectively. The increase in our selling, general and administrative expenses for the three and six months ended June 30, 2018 compared to the same

periods in 2017 are primarily due to compensation expenses including the granting and issuance of 259,551 shares of annual executive officer RSUs at a grant date fair value of $3.84 per share, resulting in approximately $1.0 million of additional non-cash, stock-based compensation expense for the three and six months ended June 30, 2018.

Research and development expenses

Research and development expense was $2.8 million and $5.3 million for the three and six months ended June 30, 2018, respectively, compared to $1.6 million and $2.9 million for the three and six months ended June 30, 2017, respectively. The increase in research and development expenses for the three and six months ended June 30, 2018 compared to the same periods in 2017 is primarily due to collaborative development services provided under our Governing Agreement with QML, for which costs incurred are included in research and development expense in the accompanying interim unaudited condensed statements of operations as our collaborative development services projects are accounted for under the FASB's guidance for collaborative arrangements.

Cash Flows for the three and six months ended June 30, 2018 and 2017

The following table summarizes the primary sources and uses of cash for each of the periods presented:

	Six Months Ended June 30,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$ (7,006,499)	$ (9,593,104)
Investing activities	(35,608,515)	4,147,661
Financing activities	38,420,770	11,335,820
Increase (decrease) in cash and cash equivalents	$ (4,194,244)	$ 5,890,377

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2018 totaled $7.0 million and reflected (i) a net loss of $9.5 million; (ii) net non-cash items of $2.2 million, consisting primarily of stock-based compensation of $1.4 million, and depreciation and amortization of $0.8 million; and (iii) a net cash inflow from changes in balances of operating assets and liabilities of $0.3 million. A decrease in accounts receivable primarily relating to the collection of profit sharing amounts receivable at year end relating to our collaborative development services programs, partially offset by a decrease in accrued liabilities and the payment of annual performance-based bonuses in the first quarter of 2018, reflect the primary items comprising the changes in balances of operating assets and liabilities.

Net cash used in operating activities for the six months ended June 30, 2017 totaled $9.6 million and reflected (i) a net loss of $11.7 million; (ii) net non-cash items of $2.0 million, consisting primarily of depreciation and amortization of $0.6 million, amortization of the discount, final payment premium and deferred financing costs on the Growth Term Loan of $0.2 million, stock-based compensation of $0.8 million, accretion of our NuvoGen discount of $0.1 million, and a provision for excess inventory of $0.2 million; and (iii) a net cash inflow from changes in balances of operating assets and liabilities of $0.1 million. The significant items comprising the changes in balances of operating assets and liabilities were increase in accounts payable, partially offset by a decrease in accrued liabilities during the period.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2018 totaled $35.6 million and was comprised primarily of purchases of available-for-sale securities of $38.1 million with proceeds received from our underwritten public offering in January 2018, partially offset by the maturity of $3.3 million in available-for-sale securities and the purchase of tooling used in manufacturing and other fixed assets during the period.

Net cash provided by investing activities for the six months ended June 30, 2017 totaled $4.1 million and was comprised primarily of proceeds from maturities of available-for-sale securities of $4.3 million during the period.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2018 totaled $38.4 million and consisted primarily of $37.7 million in net proceeds from our underwritten public offering in January 2018 and $6.6 million in net proceeds from our MidCap Term Loan in March 2018, partially offset by $6.0 million and $0.4 million in payments on our Growth Term Loan and outstanding NuvoGen obligation, respectively.

Net cash provided by financing activities for the six months ended June 30, 2017 totaled $11.3 million and consisted primarily of $14.7 million in net proceeds from our ATM Offering, offset by $3.1 million and $0.4 million in payments on our outstanding Growth Term Loan and NuvoGen obligations, respectively.

Liquidity and Capital Resources

Since our inception, our operations have primarily been financed through the issuance of our common stock, redeemable convertible preferred stock, the incurrence of debt and cash received from product sales, services revenue and other income. As of June 30, 2018, we had $40.7 million in cash, cash equivalents and investments in short-term available-for-sale securities, and $17.3 million of debt outstanding on our MidCap Term Loan, NuvoGen, capital lease and QNAH Convertible Note obligations.

Pursuant to an underwriting agreement with Leerink Partners LLC and Cantor, as representatives of the other underwriters of the agreement, we offered and sold 13,915,000 shares of our common stock at a price of $2.90 per share, including 1,815,000 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares in January 2018. The aggregate net

proceeds from the offering were approximately $37.7 million, after deducting the underwriting discounts and commissions and offering expenses. The shares of common stock described above were offered pursuant to a Registration Statement on Form S-3 (File No. 333-216977) previously filed with the SEC and declared effective by the SEC on April 6, 2017, and a prospectus supplement thereunder.

In March 2018, we entered into the MidCap Term Loan and the Midcap Revolving Loan with MidCap Financial Trust, as agent. The MidCap Term Loan provides a secured term loan facility in an aggregate principal amount of up to $20.0 million. We borrowed the first advance of $7.0 million in March 2018. Under the terms of the MidCap Term Loan, the second advance of $13.0 million will be available to us on or before September 30, 2019, subject to our satisfaction of certain conditions described in the MidCap Term Loan. All obligations under the Growth Term Loan were terminated and all outstanding amounts and fees due under the Growth Term Loan were repaid with proceeds from the MidCap Term Loan in March 2018. Amounts outstanding under the MidCap Term Loan bear interest at a floating rate equal to 7.25% per annum, plus the greater of (i) 1.25% or (ii) one-month LIBOR. Principal on each MidCap Term Loan advance is payable in 36 equal installments beginning April 1, 2020 until paid in full on March 1, 2023. The proceeds remaining from the March 2018 MidCap Term Loan funding and, if borrowed, the proceeds from MidCap Tranche 2, are expected to be used for working capital and general corporate purposes.

The MidCap Revolving Loan provides a secured revolving credit facility in an aggregate principal amount of up to $2.0 million. We may request an increase in the total commitments under the MidCap Revolving Loan by up to an additional $8.0 million, subject to agent and lender approval and the satisfaction of certain conditions. Availability of the revolving credit facility under the MidCap Revolving Loan will be based upon a borrowing base formula and periodic borrowing base certifications valuing certain of our accounts receivable and inventory, as reduced by certain reserves, if any. Though the MidCap Revolving Loan was made available upon the Company's establishment of certain lockbox arrangements in June 2018, there were no amounts outstanding under the Midcap Revolving Loan as of June 30, 2018. The proceeds of any loans under the MidCap Revolving Loan may be used for working capital and general corporate purposes.

Funding Requirements

We have had recurring operating losses and negative cash flows from operations since our inception and have an accumulated deficit of approximately $144.0 million as of June 30, 2018. As of June 30, 2018, we had cash, cash equivalents and investments in short-term available-for-sale securities of approximately $40.7 million and had current liabilities of approximately $4.9 million, plus an additional $16.9 million in long-term liabilities primarily attributable to our MidCap Term Loan, NuvoGen, and QNAH Convertible Note obligations. We believe that our existing resources will be sufficient to fund our planned operations for at least the next 12 months from the issuance of these interim unaudited condensed financial statements. However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

Until our revenue reaches a level sufficient to support self-sustaining cash flows, if ever, we may need to raise additional capital to fund our continued operations, including our product development and commercialization activities related to our current and future products. Future funding requirements will depend on a number of factors, including our ability to generate significant revenue, our ability to repay our debt obligations as they become due, the cost and timing of establishing additional sales, marketing and distribution capabilities, the ongoing cost of research and development activities, the cost and timing of regulatory clearances and approvals, the effect of competing technology and market developments, the nature and timing of companion diagnostic development collaborations we may establish and the successful commercialization of clinical diagnostic products developed and approved as a result of such collaborations and the extent to which we acquire or invest in businesses, products and technologies.

Additional capital may not be available at such times or in amounts needed by us. Even if sufficient capital is available to us, it might be available only on unfavorable terms. If we are unable to raise additional capital in the future when required and in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets.

Contractual Obligations

The following table summarizes our contractual obligations as of June 30, 2018:

	Payments due by Period				
	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
Debt obligations (1)	$18,030,897	$ 594,646	$ 9,702,247	$3,265,000	$4,469,004
Operating lease obligations (2)	1,364,842	528,492	836,350	—	—
Capital lease obligations (3)	88,700	57,164	31,536	—	—
Total contractual obligations	$19,484,439	$1,180,302	$10,570,133	$3,265,000	$4,469,004

(1) Our debt obligations include amounts due to NuvoGen under an asset purchase agreement including 2.5% interest on the remaining obligation. We have an annual obligation to pay the greater of $400,000 or 6% of sales toward the NuvoGen obligation balance until the obligation is paid in full. The table reflects remaining minimum principal payments due to NuvoGen on the remaining obligation at June 30, 2018, although actual payments could be significantly more than provided in the table to the extent that 6% of revenue exceeds $400,000. Our debt obligations further include our contractual obligations pursuant to the $7.0 million MidCap Term Loan borrowed in 2018, including contractual interest payments and a final premium fee relating to this loan. Additional amounts may be due and payable in future periods as the MidCap Revolving Loan is activated and if we meet the requirements for the second tranche of the MidCap Term Loan funding and determine that it is in our best interest to draw on those funds prior to September 30, 2019. Refer to Note 8 of our interim unaudited condensed financial statements for payments due under the MidCap Term Loan. The QNAH Convertible Note is also included in our debt obligations as of June 30, 2018. The table reflects the principal balance on the QNAH Convertible Note of $3,000,000 and interest at 3.0% per annum assuming that the balance will be paid upon maturity in October 2020 and not converted by QNAH into shares of our common stock prior to maturity.

(2) Our operating lease obligations consist of the leases for our laboratory and office facilities in Tucson, AZ expiring in 2021, as well as office copier leases.

(3) Our capital lease obligations consist of several computer equipment leases which were entered into on various dates between December 2012 and March 2018.

Off-Balance Sheet Arrangements

Through June 30, 2018, we have not entered into any off-balance sheet arrangements as defined by applicable SEC regulations.

Recent Accounting Pronouncements

See Note 2. Basis of Presentation – Recently Adopted and Recently Issued Accounting Pronouncements in the notes to the interim unaudited condensed financial statements included in this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our interim unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of financial statements in conformity with 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 financial statements and the reported amounts of revenue and expenses during the reporting period. Items subject to estimates based on judgments include, but are not limited to: revenue recognition, stock-based compensation expense, the value of the warrant liability, the resolution of uncertain tax positions, income tax valuation allowances, recovery of long-lived assets and provisions for doubtful accounts, inventory obsolescence and inventory valuation. Actual results could differ from these estimates and such differences could affect the results of operations in future periods.

There were no changes in our critical accounting policies and estimates during the three months ended June 30, 2018 from those set forth in "Critical Accounting Policies and Significant Judgments and Estimates" in our December 31, 2017 Annual Report on Form 10-K filed with the SEC on March 23, 2018 other than the adoption of the following new accounting pronouncements in the first quarter of 2018:

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than were required under previous GAAP.

In March 2016, the FASB issued ASU No. 2016-08, Revenue Recognition: Clarifying the new Revenue Standard's Principal-Versus-Agent Guidance ("ASU 2016-08"). The standard amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09. ASU 2016-08 clarifies that an entity should evaluate whether it is the principal or the agent for each specified good or service promised in a contract with a customer. As defined in ASU 2016-08, a specified good or service is "a distinct good or service (or a distinct bundle of goods or services) to be provided to the customer." Therefore, for contracts involving more than one specified good or service, the Company may be the principal in one or more specified goods or services and the agent for others.
In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing. The amendments in this standard affect the guidance in ASU 2014-09 by clarifying two aspects: identifying performance obligations and the licensing implementation guidance.

In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow Scope Improvements and Practical Expedients. The amendments in this standard affect the guidance in ASU 2014-09 by clarifying certain specific aspects of ASU 2014-09, including assessment of collectability, treatment of sales taxes and contract modifications, and providing certain technical corrections.

The new revenue standard and the standards that amend it were effective for public entities for fiscal years and interim periods within those fiscal years beginning after December 15, 2017, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company adopted ASC 606 using the full retrospective approach, which did not have an effect on 2017 revenue recognition and did not have a cumulative effect on opening equity, as the timing and measurement of revenue recognition is materially the same as under ASC 605. The Company has presented additional quantitative and qualitative disclosures regarding identified revenue streams and performance obligations for the first quarter ended June 30, 2018 (see Note 9 and Note 15). The Company has also identified and implemented changes to its business processes and internal controls relating to implementation of the new standard. For contracts where the period between when the Company transfers a promised good or service to the customer and when the customer pays is one year or less, the Company has elected the practical expedient to not adjust the promised amount of consideration for the effects of a significant financing component.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, ("ASU 2016-15"), which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted ASU No. 2016-15 as of January 1, 2018, at which time the adoption of this standard did not have a significant impact on its interim unaudited condensed financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting. The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted ASU No. 2017-09 as of January 1, 2018. The adoption of this update did not impact the Company's interim unaudited condensed financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $5.8 million at June 30, 2018, which primarily consist of U.S. Government money market funds. These funds have lower risk than traditional money market funds and are subject to fewer withdrawal penalties and limitations. Still, such interest-bearing instruments carry some degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates relating to these investments. We had $35.0 million in short-term available-for-sale securities at June 30, 2018. Our investments in short-term available-for-sale securities are at some risk for losses from possible volatility in the market. However, our investments are in a low risk portfolio comprised of U.S. Treasuries and high credit quality corporate debt securities which have an average credit rating of AA. We do not anticipate exposure to significant market risk relating to our available-for-sale securities based upon our conservative investment policy. A hypothetical 10% change in the interest rates affecting our cash, cash equivalents and short-term available-for-sale securities at June 30, 2018 would not have had a material impact on the value of our cash, cash equivalents and short-term available-for-sale securities at June 30, 2018.

Our MidCap Term Loan is variable interest rate debt for which $7.0 million was outstanding relating to the MidCap Term Loan at June 30, 2018. The MidCap Term Loan bears interest at a floating rate equal to 7.25% per annum, plus the greater of (i) 1.25% or (ii) one-month LIBOR. A hypothetical 10% change in the LIBOR rate at June 30, 2018 would not have had a material impact on our debt-related interest obligations.

As we continue to expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Historically, a majority of our revenue has been denominated in U.S. dollars, although we sell our products and services directly in certain markets outside of the United States denominated in local currency, principally the Euro. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. The effect of a 10% adverse change in exchange rates on foreign denominated receivables and payables would not have had a material impact on our results of operations during the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to potentially greater fluctuations due to changes in foreign currency exchange rates, which could increasingly affect our operating results. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported with the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of June 30, 2018, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting.

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not engaged in any material legal proceedings. However, in the normal course of business, we may from time to time be named as a party to legal claims, actions and complaints, including matters involving employment, intellectual property, vendors, customers or others.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings, before deciding to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that were not included as separate risk factors in or reflect changes to the similarly titled risk factors included in, our Annual Report on Form 10-K, filed with the SEC on March 23, 2018.

Risks Related to our Business and Strategy

We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability.*

We have incurred losses since our inception and expect to incur losses in the future. We incurred net losses of $4.1 million and $9.5 million for the three and six months ended June 30, 2018, respectively, compared to net losses of $5.8 million and $11.7 million for the three and six months ended June 30, 2017, respectively. As of June 30, 2018, we had an accumulated deficit of $144.0 million. We expect that our losses will continue for the foreseeable future as we will be required to invest significant additional funds to support product development, including development of our next generation instrument platforms, development of our new HTG EdgeSeq panels, including our initial U.S. IVD assay, development of assays pursuant to our Governing Agreement with QML, and the commercialization of our HTG EdgeSeq system and proprietary consumables. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products and services. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products and services, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

We have limited experience in marketing and selling our products, and if we are unable to successfully commercialize our products, our business may be adversely affected.*

We have limited experience marketing and selling our products. Our HTG Edge system was introduced for sale in the life sciences research market in the third quarter of 2013. Our HTG EdgeSeq chemistry was introduced for sale in the life sciences research market in the third quarter of 2014. Our dedicated HTG EdgeSeq system was introduced for sale in the life sciences research market in the fourth quarter of 2015 and has been our primary product focus since 2016. Our VERI/O service laboratory was announced in June 2016. Our first diagnostic assay, based on our HTG EdgeSeq chemistry and automated in our HTG EdgeSeq system, was introduced for sale in Europe in July 2016. We currently market our products through our own sales force in the United States and Europe and have distributors in parts of Europe and the Middle East. We intend to expand our sales and support teams in the United States and in Europe and to establish additional distributor and/or third-party contract sales team relationships in other parts of the world. However, we may not be able to market and sell our products effectively. Our sales of life science research products, diagnostic products and potential future products will depend in large part on our ability to successfully increase the scope of our marketing efforts and establish and maintain a sales force commensurate with our then applicable markets. Because we have limited experience in marketing and selling our products in the life science research market and in marketing and selling our products in the diagnostic market, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to customers is unproven. If we do not build an efficient and effective sales force and distributor relationships targeting these markets, our business and operating results will be adversely affected.

If we do not obtain regulatory clearance or approval to market our products for diagnostic purposes, we will be limited to marketing our products for research use only. In addition, if regulatory limitations are placed on our diagnostic products our business and growth will be harmed.

In many jurisdictions, including the United States, we are currently limited to marketing our HTG EdgeSeq system and proprietary profiling panels for research use only, which means that we cannot make any diagnostic or clinical claims for those products in those jurisdictions. We have sought and intend to continue to seek regulatory clearances or approvals in the United States and other jurisdictions to market certain panels for diagnostic purposes; however, we may not be successful in doing so.

The FDA regulates diagnostic kits sold and distributed through interstate commerce in the United States as medical devices. Unless an exemption applies, generally, before a new medical device may be sold or distributed in the United States, or may be marketed for a new use in the United States, the medical device must receive either FDA clearance of a 510(k) pre-market notification or pre-market approval. Thus, before we can market or distribute our profiling panels, including our mRNA and miRNA panels, as IVD kits for use by clinical testing laboratories in the United States, we must first obtain pre-market clearance or pre-market approval from the FDA. Even if or when we apply for clearance or approval from the FDA for any of our products, the process can be lengthy and unpredictable. We are working collaboratively with multiple biopharmaceutical companies to clinically validate our HTG EdgeSeq DLBCL Cell of Origin Assay, which we believe can classify DLBCL as either ABC or GCB subtype. We expect to submit the DLBCL assay for U.S. regulatory clearances or approvals at some future time if and when our work with the biopharmaceutical companies reaches an appropriate stage. We initiated a modular PMA submission process to obtain FDA approval of our HTG EdgeSeq ALK*Plus* Assay to detect certain gene fusions in lung cancer in 2016. We cannot provide any assurances that our clinical studies or collaborative development services with biopharmaceutical companies will be completed or, if completed, have the desired outcomes or that we will meet the regulatory clearance or approval timelines for either product. Further, even if we complete the requisite clinical validations and submit or complete submission of an application, we may not receive FDA clearance or approval for the commercial use of our tests on a timely basis, or at all. If we are unable to obtain regulatory clearance or approval, or if clinical diagnostic laboratories do not accept our cleared or approved tests, our ability to grow our business could be compromised.

Similarly, foreign countries have either implemented or are in the process of implementing increased regulatory controls that require that we submit applications for review and approval by foreign regulatory bodies. We obtained the right to CE mark the HTG EdgeSeq DLBCL Cell of Origin Assay EU and the HTG EdgeSeq ALK*Plus* Assay EU for sale as IVDs in Europe, in July 2016 and March 2017, respectively. If we are unable to maintain CE marking or achieve appropriate ex-U.S. approvals on any of our products for their intended commercial uses on a timely basis or at all, or if clinical diagnostic laboratories or other customers outside the United States do not accept our tests, our ability to grow our business outside of the United States could be compromised.

Clinical studies of any product candidate that we intend to market as an IVD kit may not be successful. If we are unable to successfully complete non-clinical and clinical studies of our product candidates or experience significant delays in doing so, our business will be materially harmed.

Our clinical diagnostic business prospects in the United States and other applicable jurisdictions will depend on our ability to successfully complete clinical studies for product candidates that we intend to market as IVD kits. A failure of one or more clinical studies can occur at any stage of testing. The outcome of non-clinical studies may not be predictive of the success of clinical studies, and interim results, if any, of a clinical study do not necessarily predict final results. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in non-clinical and clinical studies have nonetheless failed to obtain pre-marketing clearance or approval for their products. Completion of clinical studies, announcement of results of the studies and our ability to obtain regulatory approvals could be delayed for a variety of reasons, including:

- unsatisfactory results of any clinical study, including failure to meet study objectives;
- the failure of our principal third-party investigators to perform our clinical studies on our anticipated schedules;
- imposition of a clinical hold following an inspection of our clinical study operations or trial sites by the FDA or other regulatory authorities;
- our inability to adhere to clinical study requirements directly or with third parties, such as contract research organizations;
- different interpretations of our non-clinical and clinical data, which could initially lead to inconclusive results; and
- delays in obtaining suitable patient samples for use in a clinical study.

Our development costs will increase if we have material delays in any clinical study or if we need to perform more or larger clinical studies than planned. If the delays are significant, or if any of our products do not prove to be equivalent to a predicate device

or safe or effective, as applicable, or do not receive required regulatory approvals, our financial results and the commercial prospects for our product candidates will be harmed. Furthermore, our inability to complete our clinical studies in a timely manner could jeopardize our ability to obtain regulatory approval.

If our HTG EdgeSeq system and proprietary profiling panels fail to achieve and sustain sufficient market acceptance, or we are not able to continue to expand our service relationships with biopharmaceutical customers (including indirectly pursuant to our Governing Agreement), we will not generate expected revenue, and our prospects may be harmed.*

We are currently focused on selling our HTG EdgeSeq system and profiling panels within the life sciences research market and, where approved, in the diagnostic market. We plan to develop panels for many different disease states including companion diagnostics to determine the proper course of treatment for those diseases. We may experience reluctance, or refusal, on the part of physicians to order, and third-party payors to cover and provide adequate reimbursement for, our panels if the results of our research and clinical studies, and our sales and marketing activities relating to communication of these results, do not convey to physicians, third-party payors and patients that the HTG EdgeSeq system and related profiling panels provide equivalent or better diagnostic information than other available technologies and methodologies. We believe our panels represent an emerging methodology in diagnosing disease states, and we may have to overcome resistance among physicians to adopting it for the marketing of our products to be successful. Even if we are able to obtain regulatory approval from the FDA or other applicable regulatory authorities, the use of our panels may not become the standard diagnostic tool for those diseases on which we plan to focus our efforts.

In addition, a key component of our strategy is to develop diagnostic tools in conjunction with biopharmaceutical companies' drug development programs, to help assess the proper course of treatment for specific diseases. Even if we are successful in developing those diagnostic tools and receive regulatory approval, we still may not be successful in marketing those diagnostic tests. Furthermore, the decision to advance an underlying drug candidate through clinical trials and ultimately to commercialization is in the discretion of biopharmaceutical companies with which we collaborate. Our biopharmaceutical partners may take certain actions that could negatively impact the utility and marketability of our diagnostic tests. For example, our biopharmaceutical partners could:

- determine not to actively pursue the development or commercialization of an applicable drug candidate, including due to the failure to demonstrate sufficient efficacy, the occurrence of safety or tolerability issues, or any number of other reasons;
- fail to obtain necessary regulatory approval of an applicable drug candidate;
- obtain regulatory approval for a drug candidate in a manner that neither requires nor recommends the use of a companion diagnostic test prior to its use; or
- choose alternative diagnostic tests to market with their products instead of ours.

To the extent that we develop diagnostic assays for a biopharmaceutical company in collaboration with QML under our Governing Agreement and related statements of work, we may not have responsibility for some or all aspects of developing, marketing or commercializing any resulting diagnostic tests. In addition to this biopharmaceutical partner risk, QML may take certain actions that could negatively impact the development, utility and marketability of the applicable diagnostic tests. For example, QML could fail to satisfy or fall behind in its obligations to us or to the biopharmaceutical partner, which may delay development, regulatory approvals, market development and/or commercialization of an applicable companion diagnostic test.

Any of these events could limit our diagnostic test sales and revenues and have a material adverse effect on our business, operating results and financial condition.

We are dependent on our Governing Agreement with QML with respect to certain oncology-based diagnostic assays, and poor performance under the agreement or the termination of the agreement could negatively impact our business.*

A key strategic focus of our business is to enter into collaborative development agreements with biopharmaceutical companies for the development, manufacture and commercialization of companion diagnostic assays for use with their drug development programs. In particular, we are focused on oncology-based collaborations.

In November 2016, we entered into a Governing Agreement with QML. Under the Governing Agreement, we and QML jointly seek collaborative development agreements with biopharmaceutical companies for the development, manufacture and potential commercialization of companion diagnostic assays. QML contracts with interested biopharmaceutical companies for specified projects, and we and QML enter into statements of work for each project. Our relationship with QML under the Governing Agreement is exclusive for NGS-based diagnostic assays (or certain related research assays) in the oncology field, subject to the achievement of certain performance targets. We expect that revenues under the Governing Agreement will constitute a significant portion of our revenues over at least the next few years**.**

We have limited or no control over the amount and timing of resources that QML will dedicate to activities under the Governing Agreement, and we are subject to a number of other risks associated with our dependence on the Governing Agreement, including:

- There could be disagreements regarding the Governing Agreement, the initiation or conduct of activities under statements of work for specified projects, the achievement of milestone or other payments, the ownership of intellectual property, or research and development, regulatory, commercialization or other strategy. These disagreements might delay or terminate the development, manufacture or commercialization of companion diagnostic assays, delay or eliminate potential payments under the Governing Agreement or increase our costs under or outside of the Governing Agreement;
- QML may not allocate adequate resources or otherwise support the development of collaborations with biopharmaceutical companies, including if they no longer view our Governing Agreement as in their best financial or other interests; and
- QML may not perform as expected, including with regard to making any required payments, or performing its development or other obligations under a statement of work or under the contract with the applicable biopharmaceutical company customer and the Governing Agreement or applicable statement of work may not provide adequate protection for us or may not be effectively enforced.

In addition, we and QML have the right to terminate the Governing Agreement in certain circumstances. If the Governing Agreement is terminated early, we may not be able to find another company to assist us with the development, manufacture and commercialization of companion diagnostic assays for biopharmaceutical companies should we wish to do so. If we fail maintain a successful relationship with QML under the Governing Agreement, our development, manufacture and commercialization of companion diagnostic assays may be delayed, scaled back, or otherwise may not occur, and our anticipated revenue from the Governing Agreement could be severely limited or eliminated. In addition, we may be unable to enter into new collaborative arrangements with biopharmaceutical companies or, if necessary, modify our existing arrangements on acceptable terms. Any of these could have a material adverse effect on our business, results of operations and financial condition.

Our HTG EdgeSeq product portfolio requires the use of NGS instrumentation and reagents and could be adversely affected by actions of third party NGS product manufacturers over whom we have no control.

A key element of our strategy is to establish our HTG EdgeSeq system as the best sample and library preparation method for clinical applications of next generation sequencers. We depend at least in part on the availability of NGS instrumentation and reagents, and the ability of our HTG EdgeSeq products to operate seamlessly with NGS instrumentation. Any significant interruption or delay in the ability of our HTG EdgeSeq products to operate on or with NGS instrumentation could reduce demand for our products and result in a loss of customers.

Our reputation, and our ability to continue to establish or develop our technology for clinical applications of next generation sequencers, are dependent upon the availability of NGS instrumentation and the reliable performance of our products with NGS instrumentation. We are not able to control the providers of NGS instrumentation, which increases our vulnerability to interoperability problems with the products that they provide. For example, providers of NGS instruments may discontinue existing products, or introduce new NGS instrumentation products with little or no notice to us. This may cause some of our products not to be operable with one or more NGS instruments or may adversely affect regulatory approvals of our future IVD HTG EdgeSeq products, potentially for extended periods of time. Any interruption in the ability of our products to operate on NGS instruments could harm our reputation or decrease market acceptance of our products, and our business, financial condition and operating results may be materially and adversely affected. We also could experience additional expense in developing new products or changes to existing products to meet developments in NGS instrumentation, and our business, financial condition and operating results may be materially and adversely affected.

Current medical device regulation in the United States and other jurisdictions requires manufacturers of IVD molecular profiling tests that use NGS detection, referred to as NGS IVD tests, to include in regulatory submissions, technical information about the NGS products that are required for performance of, but are not supplied with, the NGS IVD test. These regulatory agencies also require that the NGS instrumentation have “locked” software for the detection of the NGS IVD test results. Thus, to obtain regulatory approval for NGS IVD tests, manufacturers like us, currently must have arrangements with NGS product manufacturers to gain access to technical information and NGS instrument software. We currently have agreements with two NGS product manufacturers that grant us rights to develop, manufacture and sell future HTG EdgeSeq NGS IVD tests in specified fields, subject to, among other things, the NGS product manufacturers’ rights to terminate such agreements and discontinue products or implement product design changes that could adversely affect our HTG EdgeSeq NGS IVD tests. There can be no assurance that our agreements with these NGS product manufacturers, or any future NGS product manufacturers that we contract with, will not be terminated earlier than we currently expect, that a NGS product manufacturer will perform its contractual duties to us, or that we will otherwise receive the benefits we anticipate receiving under those agreements. In addition, if regulatory agencies do not change their requirements for NGS IVD test

approval or clearance and the NGS instrument manufacturers close their systems to third party NGS IVD test development (in general or with specific NGS IVD test manufacturers) and we are not able to maintain or enforce our agreements with such manufacturers, we may not be able to meet our commercial goals and our business, financial condition and operating results may be materially and adversely affected.

The development of future products is dependent on new methods and/or technologies that we may not be successful in developing.*

We are planning to expand our product offerings in the fields of detecting expressed gene rearrangements (e.g., gene fusions and/or insertions) and genomic or expressed DNA mutations. We believe we have successfully demonstrated that our technology is able to detect certain expressed gene rearrangements with our HTG EdgeSeq ALK*Plus* Assay EU now available in Europe, and genomic DNA mutations with our HTG EdgeSeq EGFR, KRAS and BRAF Mutation Assay service offering. Nevertheless, there are other potential applications for the foregoing technologies and opportunity for additional technology developments, such as detection of expressed DNA mutations, methods to detect mutation load and microsatellite instability and multiparameter testing methods, that we consider when planning our product pipeline. We cannot guarantee that we will be able to successfully develop additional applications or new technologies on a commercial scale. If we are unsuccessful at developing additional applications involving gene rearrangements or genomic DNA mutations, or developing technology to detect expressed DNA mutations, mutation load and microsatellite instability or developing multiparameter testing methods we may be limited in the breadth of additional products we can offer in the future, which could impact our future revenues and profits.

We intend to develop a new version of our HTG EdgeSeq system that is expected to target the lower-volume throughput lab market by enabling efficient molecular profiling of smaller quantity batches of samples. In the third quarter of 2016, we suspended the development of the Project JANUS program. If we are unable to resume or successfully develop this new version of our HTG EdgeSeq system on a timely basis, automation of our new chemistry could be delayed and our addressable market could be limited, which could harm our business, results of operations and financial condition.

We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.

Our success depends on our ability to develop new products and applications for our technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems. Existing or future markets for our products, including gene expression analysis, liquid-based specimen analysis (e.g., plasma, blood and urine) and single-cell analysis, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or effectively manage the transitions to new product offerings, our revenues and results of operations will be adversely impacted.

Competitors may respond more quickly and effectively than we do to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

If we do not successfully manage the development and launch of new products, our financial results could be adversely affected.

We face risks associated with launching new products and with undertaking to comply with regulatory requirements for certain of our products. If we encounter development or manufacturing challenges, adjust our product development priorities, or discover errors during our product development cycle, the product launch date(s) may be delayed or certain product development projects may be terminated. The expenses or losses associated with unsuccessful product development or launch activities or lack of market acceptance of our new products could adversely affect our business or financial condition.

If we do not achieve, sustain or successfully manage our anticipated growth, our business and growth prospects will be harmed.

Our current personnel, systems and facilities may not be adequate to support our business plan and future growth. Our need to effectively manage our operations, growth and various projects requires that we, among other things:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities effectively and in a cost-effective manner;
- manage our relationship with third parties related to the commercialization of our products; and
- manage our development efforts effectively while carrying out our contractual obligations to contractors and other third parties.

Moreover, growth will place significant strains on our management and our operational and financial systems and processes. For example, expanded market penetration of our HTG EdgeSeq system and related proprietary panels, and future development and approval of diagnostic products, are key elements of our growth strategy that will require us to hire and retain additional sales and marketing, regulatory, manufacturing and quality assurance personnel. If we do not successfully forecast the timing and cost of the development of new panels and diagnostic products, the regulatory clearance or approval for product marketing of any future diagnostic products or the demand and commercialization costs of such products, or manage our anticipated expenses accordingly, our operating results will be harmed.

Our future success is dependent upon our ability to expand our customer base and introduce new applications.*

Our current customer base is primarily composed of biopharmaceutical companies (including those contracted by QML pursuant to our Governing Agreement), academic institutions and molecular labs that perform analyses using or directly or indirectly obtain services based on our HTG EdgeSeq system and consumables for research use only, which means that the products or data from services may not be used for clinical diagnostic purposes. In July 2016, we obtained CE marking in Europe for our HTG EdgeSeq system and HTG EdgeSeq DLBCL Cell of Origin Assay EU. In March 2017, we obtained CE marking in Europe for our HTG EdgeSeq ALK*Plus* Assay EU. These products may now be used by customers for diagnostic purposes in Europe. Currently, we do not intend to and, where applicable, do not have appropriate licenses or permits to conduct diagnostic testing services. Our success will depend, in part, upon our ability to increase our market penetration among our customer bases and to expand our market by developing and marketing new clinical diagnostic tests and RUO applications (whether product or service), and to introduce diagnostic products into clinical laboratories in the United States and other jurisdictions after obtaining the requisite regulatory clearances or approvals. We may not be able to successfully complete development of or commercialize any of our planned future tests and applications. To achieve these goals, we will need to conduct substantial research and development, conduct clinical validation studies, expend significant funds, expand and scale-up our research, development, service and manufacturing processes and facilities, expand the number of projects under our Governing Agreement, expand and train our sales force; and seek and obtain regulatory clearance or approvals of our new tests and applications, as required by applicable regulations. Additionally, we must demonstrate to laboratory directors, physicians and third-party payors that our current and any future diagnostic products are effective in obtaining clinically relevant information that can inform treatment decisions, and that our HTG EdgeSeq system and related panels can enable an equivalent or superior approach than other available technology. Furthermore, we expect that a combination of increasing the installed base of our HTG EdgeSeq systems, expanding the number of projects under our Governing Agreement, and entering into additional service and custom RUO assay design agreements with biopharmaceutical customers will drive increased demand for our relatively high margin panels. If we are not able to successfully increase our installed base and biopharmaceutical customer relationships, then sales of our products and services, and our margins for these revenue items may not meet expectations. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products, including diagnostic products or services, would adversely affect our ability to improve our operating results.

Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price.*

Investors should consider our business and prospects considering the risks and difficulties we expect to encounter in the new, uncertain and rapidly evolving markets in which we compete. Because these markets are new and evolving, predicting their future growth and size is difficult. We expect that our visibility into future sales of our products, including volumes, prices and product mix between instruments, consumables and services, will continue to be limited and could result in unexpected fluctuations in our quarterly and annual operating results.

Numerous other factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, QML and another customer accounted for 59% and 11% of our revenue, respectively, for the three and six months ended June 30, 2018, and for 59% and 15% of our accounts receivable balance, respectively, as of June 30, 2018. If orders from our top customers or the number of collaboration projects with QML are reduced or discontinued, our revenue in future periods may materially decrease. Fluctuations in our operating results may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Factors that may contribute to fluctuations in our operating results include many of the risks described under the caption "Risk Factors – Risks Related to Our Business and Strategy" of this report. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. Our products involve a significant capital commitment from our customers or may depend on customer studies that have variable or indefinite timelines and accordingly, involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. Also, activities performed under our Governing Agreement involve significant resource commitments by us and depend on QML activities over which we have limited control and on biopharmaceutical customer activities and studies that have variable or indefinite timelines and outcomes. We may expend significant effort in attempting to meet our development obligations under the Governing Agreement, the respective payments for which may occur in a different period. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on our past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected.

Our sales cycle is lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

Our sales process involves numerous interactions with multiple individuals within any given organization, and often includes in-depth analysis by potential customers of our products (where in some instances we will provide a demonstration unit for their use and evaluation), performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors, the capital investment required in purchasing our instrument and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly and be up to 12 months or longer. Given the length and uncertainty of our sales cycle, we have in the past experienced, and likely will in the future experience, fluctuations in our product and product-related services revenue on a period-to-period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems or service providers or to purchase systems or services other than ours. The revenue that we expect to earn from our collaborative development services are also subject to an extended, variable timeline based on each project agreement, which will likely result in fluctuations in our collaborative development services revenue on a period-to-period basis as well.

If the utility of our HTG EdgeSeq system, proprietary profiling panels, services and solutions in development is not supported by studies published in peer-reviewed medical publications, the rate of adoption of our current and future products and the rate of reimbursement of our future products by third-party payors may be negatively affected.

We anticipate that we will need to maintain a continuing presence in peer-reviewed publications to promote adoption of our products by biopharmaceutical companies, academic institutions and molecular labs and to promote favorable coverage and reimbursement decisions. We believe that peer-reviewed journal articles that provide evidence of the utility of our current and future products or the technology underlying the HTG EdgeSeq system, consumables and services are important to our commercial success. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about our HTG EdgeSeq system, our current panels and services and our future solutions, and demonstrate the research and clinical benefits of these solutions. Our customers may not adopt our current and future solutions, and third-party payors may not cover or adequately reimburse our future products, unless they determine, based on published peer-reviewed journal articles and the experience of other researchers and clinicians, that our products provide accurate, reliable, useful and cost-effective information. Peer-reviewed publications regarding our products and solutions may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from studies that would be the subject of the article. If our current and future product and product-related service solutions or the technology underlying such products and services do not receive sufficient favorable exposure in peer-reviewed publications, the rate of research and clinician adoption and positive coverage and reimbursement decisions could be negatively affected.

We provide our HTG EdgeSeq system and profiling panels free of charge or through other arrangements to customers or key opinion leaders through evaluation agreements or reagent rental programs, and these programs may not be successful in generating recurring revenue from sales of our systems and proprietary panels.

We sell our HTG EdgeSeq system and profiling panels under different arrangements to expand our installed base and facilitate the adoption of our platform.

In some instances, we provide equipment free of charge under evaluation agreements for a limited period of time to permit the user to evaluate the system for their purposes in anticipation of a decision to purchase the system. We retain title to the equipment under such arrangements unless the evaluator purchases the equipment, and in most cases, require evaluation customers to purchase a minimum quantity of consumables during the evaluation period.

When we place a system under a reagent rental agreement, we install equipment in the customer's facility without a fee and the customer agrees to purchase consumable products at a stated priced over the term of the agreement. While some of these agreements did not historically contain a minimum purchase requirement, we have included a minimum purchase requirement in all current reagent rental agreements, and will continue to do so in the future. We retain title to the equipment and such title is transferred to the customer at no additional charge at the end of the initial arrangement. The cost of the instrument under the agreement is expected to be recovered in the fees charged for consumables, to the extent sold, over the term of the agreement.

Other arrangements might include a research agreement whereby an academic collaborator agrees to provide biological samples in exchange for the use of an HTG EdgeSeq system at no cost in furtherance of the collaborator's professional goals and/or the educational or research objectives of an applicable institution.

Any of the foregoing arrangements could result in lost revenues and profit and potentially harm our long-term goal of achieving profitable operations. In addition, despite the fact we require customers who receive systems we continue to own to carry insurance sufficient to protect us against any equipment losses, we cannot guarantee that they will maintain such coverage, which may expose us to a loss of the value of the equipment in the event of any loss or damage.

There are instances where we provide our systems to key opinion leaders free of charge, to gather data and publish the results of their research to assist our marketing efforts. We have no control over some of the work being performed by these key opinion leaders, or whether the results will be satisfactory. It is possible that the key opinion leader may generate data that is unsatisfactory and could potentially harm our marketing efforts. In addition, customers may from time to time create negative publicity about their experience with our systems, which could harm our reputation and negatively affect market perception and adoption of our platform.

Placing our HTG EdgeSeq systems under evaluation agreements, under reagent rental agreements or with our key opinion leaders without receiving payment for the instruments could require substantial additional working capital to provide additional units for sale to our customers.

Our strategy of developing companion diagnostic products may require large investments in working capital and may not generate any revenues.

A key component of our strategy is the development of companion diagnostic products designed to determine the appropriate patient population for administration of a particular therapeutic to more successfully treat a variety of illnesses. We have an exclusive arrangement with QML to develop certain companion diagnostic products for biopharmaceutical companies under our Governing Agreement. Otherwise, we may choose to independently develop companion diagnostic products with or without a biopharmaceutical partner. Successfully developing a companion diagnostic product depends both on regulatory approval for administration of the therapeutic, as well as regulatory approval of the diagnostic product. Even if we are successful in developing products that would be useful as companion diagnostic products, and potentially receive regulatory approval for such products, the biopharmaceutical companies that develop the corresponding therapeutics may ultimately be unsuccessful in obtaining regulatory approval for any such therapeutic, or, even if successful, select a competing technology to use in their regulatory submission instead of ours. The development, especially the independent development, of companion diagnostic products requires a significant investment of working capital which may not result in any future income. This could require us to raise additional funds which could dilute our current investors or could impact our ability to continue our operations in the future.

Our current business depends on levels of research and development spending by academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.*

Our revenue is currently derived from sales of our HTG EdgeSeq system and related proprietary panels, the design of custom RUO assays and sample processing for research applications to biopharmaceutical companies, academic institutions and molecular labs, predominantly in the United States and Europe, and collaborative development services. The demand for our products and services will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- changes in government programs that provide funding to research institutions and companies;
- macroeconomic conditions and the political climate;

- changes in the regulatory environment;
- differences in budgetary cycles;
- market-driven pressures to consolidate operations and reduce costs; and
- market acceptance of relatively new technologies, such as ours.

We believe that any uncertainty regarding the availability of research funding may adversely affect our operating results and may adversely affect sales to customers or potential customers that rely on government funding. In addition, academic, governmental and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could result in spending reductions, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers to purchase our products or services. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. Any decrease in our customers' budgets or expenditures, or in the size, scope or frequency of capital or operating expenditures, could materially and adversely affect our business, operating results and financial condition.

As part of our current business model, we intend to seek to enter into strategic development collaborations and licensing arrangements with third parties to develop diagnostic tests.

We have relied, and expect to continue to rely, on strategic development collaborations and licensing agreements with third parties to develop or in-license technologies based on which products or services we may develop or offer. We have entered into agreements with third parties to facilitate or enable our development of assays, and ultimately diagnostic tests, to aid in the diagnosis of oncology diseases, such as breast cancer and melanoma, and other diseases. We intend to enter into additional similar agreements with life sciences companies, biopharmaceutical companies and other researchers for future diagnostic products. However, we cannot guarantee that we will enter into any additional agreements. In particular, our life sciences research or biopharmaceutical customers are not obligated to collaborate with us or license technology to us, and they may choose to develop diagnostic products themselves or collaborate with our competitors. Establishing development collaborations and licensing arrangements is difficult and time-consuming. Discussions may not lead to development collaborations or licenses on favorable terms, or at all. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. To the extent that we enter new collaborative development or licensing agreements, they may never result in the successful development or commercialization of future tests or other products for a variety of reasons, including because our collaborators may not succeed in performing their obligations or may choose not to cooperate with us. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Moreover, to the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others would be limited. Even if we establish new relationships, they may never result in the successful development or commercialization of future tests or other products. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

Our research and development efforts will be hindered if we are not able to contract with third parties for access to archival patient samples.

Our future development of products for clinical indications will require access to archival patient samples for which data relevant to the clinical indication of interest is known. We rely on our ability to secure access to these archived patient samples, including FFPE tissue, plasma, serum, whole blood preserved in PAXgene, or various cytology preparations, together with the information pertaining to the clinical outcomes of the patients from which the samples were taken. Owners or custodians of relevant samples may be difficult to identify and/or identified samples may be of poor quality or limited in number or amount. Additionally, others compete with us for access to these samples for both research and commercial purposes. Even when an appropriate cohort of samples is identified, the process of negotiating access to these samples can be lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, and intellectual property ownership. In addition, in some instances the cost to acquire samples can be prohibitively expensive. If we are not able to negotiate access to archived patient samples on a timely basis and on acceptable terms, or at all, or if our competitors or others secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

The life sciences research and diagnostic markets are highly competitive. We face competition from enhanced or alternative technologies and products, which could render our products and/or technologies obsolete. If we fail to compete effectively, our business and operating results will suffer.

We face significant competition in the life sciences research and diagnostics markets. We currently compete with both established and early-stage life sciences research companies that design, manufacture and market instruments and consumables for

gene expression analysis, liquid-based specimen analysis (e.g., plasma, blood and urine), single-cell analysis, PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well-established laboratory techniques such as microarrays or qPCR as well as newer technologies such as next generation sequencing. We believe our principal competitors in the life sciences research market are Agilent Technologies, Inc., ArcherDx, Inc., BioRad Laboratories, Fluidigm Corporation, Foundation Medicine, Inc., Genomic Health, Illumina, Inc., Abbott Molecular, Luminex Corporation, Affymetrix, Inc., NanoString Technologies, Inc., entities owned and controlled by QIAGEN N.V., Roche Diagnostics, a division of the Roche Group of companies, Personal Genome Diagnostics and Thermo Fisher Scientific, Inc. In addition, there are several other market entrants in the process of developing novel technologies for the life sciences market. One or more of our competitors could develop a product that is superior to a product we offer or intend to offer or our technology and products may be rendered obsolete or uneconomical by advances in existing technologies.

Within the diagnostic market, there are competitors that manufacture systems for sales to hospitals and laboratories and other competitors that offer tests conducted through CLIA laboratories. We will also compete with commercial diagnostics companies. Most of our current competitors are either publicly traded, or are divisions of publicly traded companies, and enjoy a number of competitive advantages over us, including:

- greater name and brand recognition, financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale, and lower cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

- cost of capital equipment;
- cost of consumables and supplies;
- reputation among customers;
- innovation in product offerings;
- flexibility and ease-of-use;
- accuracy and reproducibility of results; and
- compatibility with existing laboratory processes, tools and methods.

We believe that additional competitive factors specific to the diagnostics market include:

- breadth of clinical decisions that can be influenced by information generated by tests;
- volume, quality, and strength of clinical and analytical validation data;
- availability of coverage and adequate reimbursement for testing services; and
- economic benefit accrued to customers based on testing services enabled by products.

Our products may not compete favorably, and we may not be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We are dependent on a single third-party supplier for a certain subcomponent of our systems and the loss of this supplier could harm our business.

We currently rely on a single supplier to supply a subcomponent used in our HTG EdgeSeq processors. While we periodically forecast our needs for this subcomponent, our contract with this supplier, which may be a standard purchase order, does not commit them to carry inventory or make available any particular quantities, and the supplier may give other customers' needs higher priority

than ours and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If we were to lose this supplier, we may not be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, or at all. If we should encounter delays or difficulties in securing the quality and quantity of subcomponent we require for our processors, our supply chain would be interrupted which would adversely affect our sales. A loss of this supplier could significantly delay the delivery of our HTG EdgeSeq processor, which in turn would materially affect our ability to generate revenue. If any of these events occur, our business and operating results could be materially harmed.

We may encounter manufacturing difficulties that could impede or delay production of our HTG EdgeSeq systems.

We began manufacturing our HTG EdgeSeq system internally in 2016. We have limited experience with manufacturing the system and our internal manufacturing operations may encounter difficulties involving, among other things, scale-up of manufacturing processes, production efficiency and output, regulatory compliance, quality control and quality assurance, and shortages of qualified personnel. Any failure in our planned internal manufacturing operations could cause us to be unable to meet demand for these systems, delay the delivery of the system to customers, and harm our business relationships and reputation.

If we encounter difficulties in our planned internal manufacturing operations, we may need to engage a third-party supplier, provided we cannot be sure we will be able to do so in a timely manner, or at all, or on favorable terms.

Any of these factors could cause us to delay or suspend production of our HTG EdgeSeq system, entail unplanned additional costs and materially harm our business, results of operations and financial condition.

If our Tucson facilities become unavailable or inoperable, the manufacturing of our instrument and consumable products or our ability to process sales orders will be interrupted and our business could be materially harmed.

We manufacture our consumable products and our HTG EdgeSeq system and perform our RUO profiling and collaborative development services in our Tucson, Arizona facilities. In addition, our Tucson facilities are the center for order processing, receipt of critical components of our HTG EdgeSeq instrument and shipping products to customers. We do not have redundant facilities. Damage or the inability to utilize our Tucson facilities and the equipment we use to perform research, development or services and manufacture our products could be costly, and we would require substantial lead-time to repair or replace this facility and equipment. The Tucson facilities may be harmed or rendered inoperable by natural or man-made disasters, including flooding, wind damage, power spikes and power outages, which may render it difficult or impossible for us to perform these critical functions for some period of time. The inability to manufacture consumables or instruments, process customer samples, perform development services under our Governing Agreement or ship products to customers for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

We expect to generate a portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.*

During the three and six months ended June 30, 2018, approximately 74% and 76% of the Company's revenue was generated from sales originated by customers located outside of the United States, respectively, compared with 34% and 27% for the three and six months ended June 30, 2017, respectively. We expect that a percentage of our future revenue will continue to come from international sources, driven in part by activities conducted pursuant to our Governing Agreement, and we expect to expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export and import restrictions;
- various reimbursement, pricing and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers, including transfer pricing, value added and other tax systems, double taxation and restrictions and/or taxation on repatriation of earnings;
- tariffs, customs charges, bureaucratic requirements and other trade barriers;
- difficulties and costs of staffing and managing foreign operations, including difficulties and costs associated with foreign employment laws;
- increased financial accounting and reporting burdens and complexities; and
- difficulties protecting, procuring, or enforcing intellectual property rights, including from reduced or varied protection for intellectual property rights in some countries.

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Historically, most of our revenue has been denominated in U.S. dollars, although we have sold our products and services in local currency outside of the United States, principally the Euro. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. As our operations in countries outside of the United States grows, our results of operations and cash flows will increasingly be subject to fluctuations due to changes in foreign currency exchange rates, which could negatively impact our results of operations in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of an offsetting change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars.

If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer. Moreover, we cannot be certain that the investment and additional resources required in establishing operations in other countries will produce desired levels of revenue or profitability.

In addition, any failure to comply with applicable legal and regulatory obligations could negatively impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities.

We rely on distributors for sales of our products in several markets outside of the United States.

We have established exclusive and non-exclusive distribution agreements for our HTG EdgeSeq platform and related profiling panels within parts of Europe and the Middle East. We intend to continue to grow our business internationally, and to do so, in addition to expanding our own direct sales and support team, we plan to attract additional distributors and sales partners to maximize the commercial opportunity for our products. We cannot guarantee that we will be successful in attracting desirable distribution and sales partners or that we will be able to enter into such arrangements on favorable terms. Distributors and sales partners may not commit the necessary resources to market and sell our products to the level of our expectations or may favor marketing the products of our competitors. If current or future distributors or sales partners do not perform adequately, or we are unable to enter into effective arrangements with distributors or sales partners in particular geographic areas, we may not realize long-term international revenue growth.

Limitations in the use of our products could harm our reputation or decrease market acceptance of our products; undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products are subject to the limitations set forth in the product labeling, which may not satisfy the needs of all customers. For example, in the past we have introduced new panels that initially were intended to be used with specific sample types. Because our customers desire that our panels be broadly applicable to many biological sample types, these initial limitations could harm our reputation or decrease market acceptance of our products. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise, which could harm our business and operating results.

Similarly, our products may contain undetected errors or defects when first introduced or as new versions are released. Since our current customers use our products for research and, if cleared or approved for diagnostic applications, disruptions or other performance problems with our products may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material

liability claim or other occurrence that harms our reputation or decreases market acceptance of our products could harm our business and operating results.

The sale and use of products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to adequately perform the analysis for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure investors that our product liability insurance could adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

We may need to raise additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available, financing terms may lead to significant dilution of our stockholders' equity.*

We are not profitable and have had negative cash flow from operations since our inception. To fund our operations and develop and commercialize our products, we have relied primarily on equity and debt financings and revenue generated from the sale of our HTG EdgeSeq systems, proprietary consumables, related services and collaborative development service arrangements with biopharmaceutical company customers (directly or indirectly via the Governing Agreement). We currently anticipate that our cash and cash equivalents, including funds generated in our January 2018 public offering, will be sufficient to enable us to fund our operations for at least the next 12 months. We may need to obtain additional funds to finance our operations in the future if our estimates of the amount of cash necessary to fund our operations and development and commercialization activities prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Additional capital may not be available at such times or amounts as needed by us. Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt financing into which we enter could be dilutive to our existing stockholders. Any future debt financing into which we enter may impose covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may need to relinquish rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired, and we may be required to cease operations, curtail one or more product development or commercialization programs, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all of our assets. Any of these factors could harm our operating results.

Payments under the instruments governing our indebtedness may reduce our working capital. In addition, a default under our MidCap Credit Facility could cause a material adverse effect on our financial position.*

Pursuant to the terms of an asset purchase agreement with NuvoGen, we agreed to annually pay NuvoGen the greater of $400,000 or 6% of our yearly revenue until the total aggregate cash compensation paid to NuvoGen under the agreement equals $15.0 million. To date, we have paid NuvoGen approximately $7.3 million. Payments to NuvoGen will result in a reduction in our working capital as we continue to make payments on this obligation.

Pursuant to the terms of the $3.0 million QNAH Convertible Note that we issued in October 2017, we will be required to repay the entire outstanding principal amount of the note and unpaid accrued interest thereon in October 2020, subject potentially to the terms of a future subordination agreement between QNAH and our senior lenders, provided QNAH may, at its election, convert all or any portion of the outstanding principal balance of the note and unpaid accrued interest at any time prior to the maturity date into shares of our common stock at a conversion price of $3.984 per share. Repayment of this note and unpaid accrued interest thereon at maturity would result in a reduction in our working capital, which could be significant depending on our cash position on the maturity date.

The MidCap Credit Facility requires us, and any debt arrangements we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness or modify existing debt agreements;
- amend or modify certain material agreements;

- engage in additional lines of business;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- change certain key management personnel or organizational documents; and
- engage in transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. If we default under our obligations under the MidCap Term Loan, the lender could proceed against the collateral granted to them to secure our indebtedness or declare all obligation under the MidCap Term Loan to be due and payable. In certain circumstances, procedures by the lender could result in a loss by us of all of our equipment and inventory, which are included in the collateral granted to the lender. In addition, upon any distribution of assets pursuant to any liquidation, insolvency, dissolution, reorganization or similar proceeding, the holders of secured indebtedness will be entitled to receive payment in full from the proceeds of the collateral securing our secured indebtedness before the holders of other indebtedness or our common stock will be entitled to receive any distribution with respect thereto.

The enactment of U.S. tax reform in 2017 resulted in changes in the U.S. taxation of domestic and international business activities which could materially impact our future financial position and results of operations.

The 2017 Tax Act, which was signed into law on December 22, 2017, significantly revises the Internal Revenue Code of 1986, as amended (the "IRC"). The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including a reduction of the federal statutory rates from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income, elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. It is also unknown if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is likewise uncertain and could be adverse. We urge you to consult with a legal and/or tax advisor with respect to this legislation and the potential consequences of investing in our common stock.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2017, we had federal net operating loss carryforwards ("NOLs") to offset future taxable income of approximately $122.0 million, which will begin to expire in 2021 if not utilized. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the IRC, a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period) is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We believe we may have already experienced one or more ownership changes and may in the future experience one or more additional ownership changes, and thus, our ability to utilize pre-ownership change NOLs and other pre-ownership change tax attributes to offset post-ownership change income may be limited. Such limitations may cause a portion of our NOL and credit carryforwards to expire. In addition, future changes in our stock ownership, including as a result of future financings, as well as changes that may be outside of our control, could result in ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have limited experience with respect to business, product or technology acquisitions or the formation of collaborations, strategic alliances and joint ventures or investing in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;

- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

If any members of our management team were to leave us or we are unable to recruit, train and retain key personnel, we may not achieve our goals.*

Our future success depends on our ability to recruit, train, retain and motivate key personnel, including our senior management, research and development, manufacturing, service and sales and marketing personnel. If we were to lose one or more of our key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Competition for qualified personnel is intense, and we may not be able to attract talent. Our growth depends, in part, on attracting, retaining and motivating highly trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers, including new biopharmaceutical company customers. In particular, the commercialization of our HTG EdgeSeq system and related panels requires us to continue to establish and maintain sales and support teams to optimize the markets for research tools and, where approved, diagnostic assays, and to fully optimize a broad array of diagnostic market opportunities as we receive approval for any future diagnostic products. We do not maintain fixed term employment contracts or, except for our Chief Executive Officer, key man life insurance relating to any of our employees. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to retain our management team or to attract, train, retain and motivate other qualified personnel could materially harm our operating results and growth prospects.

Our operating results may be harmed if we are required to collect sales, services or other related taxes for our products and services in jurisdictions where we have not historically done so.

We do not believe that we are required to collect sales, use, services or other similar taxes from our customers in certain jurisdictions. However, one or more countries or states may seek to impose sales, use, services, or other tax collection obligations on us, including for past sales. A successful assertion by one or more jurisdictions that we should collect sales or other taxes on the sale of our products and services could result in substantial tax liabilities for past sales and decrease our ability to compete for future sales. Each country and each state has different rules and regulations governing sales and use taxes and these rules and regulations are subject to varying interpretations that may change over time. We review these rules and regulations periodically and, when we believe sales and use taxes apply in a particular jurisdiction, voluntarily engage tax authorities in order to determine how to comply with their rules and regulations. We cannot assure you that we will not be subject to sales and use taxes or related penalties for past sales in jurisdictions where we presently believe sales and use taxes are not due.

Providers of goods or services are typically held responsible by taxing authorities for the collection and payment of any applicable sales and similar taxes. If one or more taxing authorities determines that taxes should have, but have not, been paid with respect to our products and services, we may be liable for past taxes in addition to being required to collect sales or similar taxes in respect of our products and services going forward. Liability for past taxes may also include substantial interest and penalty charges. Our customer contracts provide that our customers must pay all applicable sales and similar taxes. Nevertheless, customers may be reluctant to pay back taxes and may refuse responsibility for interest or penalties associated with those taxes or we may determine that it would not be feasible to seek reimbursement. If we are required to collect and pay back taxes and the associated interest and penalties and if our customers do not reimburse us for all or a portion of these amounts, we will have incurred unplanned expenses that may be substantial. Moreover, imposition of such taxes on our products and services going forward will effectively increase the cost of such products and services to our customers.

Many states are also pursuing legislative expansion of the scope of goods and services that are subject to sales and similar taxes as well as the circumstances in which a vendor of goods and services must collect such taxes. Furthermore, legislative proposals have been introduced in Congress that would provide states with additional authority to impose such taxes. Accordingly, it is possible that either federal or state legislative changes may require us to collect additional sales and similar taxes from our customers in the future.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, automobile, umbrella, workers' compensation, crime (including cybercrime), fiduciary, products liability, pollution, errors and omissions and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our HTG EdgeSeq systems and consumables to our customers and, as applicable, customers' samples to our laboratory, and for enhanced tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any instrumentation, consumables or samples, it would be costly to replace such instrumentation or consumables in a timely manner and may be difficult to replace customers' samples lost or damaged in shipping, and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products or receive recipient samples on a timely basis.

We face risks related to handling of hazardous materials and other regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We could discover that we or an acquired business is not in material compliance with these regulations. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, and any liability could exceed our resources or any applicable insurance coverage we may have, which events could adversely affect our business.

Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.

Our business requires manipulating, analyzing and storing large amounts of data. In addition, we rely on an enterprise software system to operate and manage our business. We also maintain personally identifiable information about our employees. Our business therefore depends on the continuous, effective, reliable and secure operation of our computer hardware, software, networks, Internet servers and related infrastructure. To the extent that our hardware and software malfunction or access to our data by internal personnel is interrupted, our business could suffer. The integrity and protection of our employee and company data is critical to our business and employees have a high expectation that we will adequately protect their personal information. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. Maintaining compliance with applicable security and privacy regulations may increase our operating costs. Although our computer and communications software are protected through physical and software safeguards, it is still vulnerable to natural or man-made hazards, such as fire, storm, flood, power loss, wind damage, telecommunications failures, physical or software break-ins, software viruses and similar events. These events could lead to the unauthorized access, disclosure and use of non-public information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. In addition, any sustained disruption in internet access provided by other companies could harm our business.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our research use only products for the life sciences market could become subject to regulation as medical devices by the FDA or other regulatory agencies in the future which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our life sciences business and results of operations.

In the United States, our products are currently labeled and sold for research use only, and not for the diagnosis or treatment of disease, and are sold to a variety of parties, including biopharmaceutical companies, academic institutions and molecular labs. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled, "For Research Use Only. Not for use in diagnostic procedures," the regulations do not otherwise subject such products to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO products or how they are enforced may require us to change our business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only" (the "RUO Guidance") which highlights the FDA's interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA's position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO status held by the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO tests until we are in compliance, which would reduce our revenues, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, the FDA's proposed implementation for a new framework for the regulation of LDTs may negatively impact the LDT market and thereby reduce demand for RUO products.

If the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval requested by us in a timely manner, or at all.

Approval and/or clearance by the FDA and foreign regulatory authorities for any diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

Before we begin to label and market our products for use as clinical diagnostics in the United States, including as companion diagnostics, unless an exemption applies, we will be required to obtain either 510(k) clearance or PMA from the FDA. In addition, we may be required to seek FDA clearance for any changes or modifications to our products that could significantly affect their safety or effectiveness or would constitute a change in intended use. The 510(k) clearance processes can be expensive, time-consuming and uncertain. In addition to the time required to conduct clinical studies, if necessary, it generally takes from four to twelve months from submission of an application to obtain 510(k) clearance; however, it may take longer and 510(k) clearance may never be obtained. Even if the FDA accepts a 510(k) submission for filing, the FDA may request additional information or clinical studies during its review. Our ability to obtain additional regulatory clearances for new products and indications may be significantly delayed or may never be obtained. In addition, we may be required to obtain PMAs for new products or product modifications. The requirements of the more rigorous PMA process could delay product introductions and increase the costs associated with FDA compliance. As with all IVD products, the FDA reserves the right to redefine the regulatory path at the time of submission or during the review process and could require a more burdensome approach. Even if we were to obtain regulatory approval or clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

A 510(k) clearance or PMA submission for any future medical device product would likely place substantial restrictions on how the device is marketed or sold, and we will be required to continue to comply with extensive regulatory requirements, including, but not limited to QSRs, registering manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, adverse event and medical device reporting requirements and corrections and removals. We cannot assure you that we will successfully maintain the clearances or approvals we may receive in the future. In addition, any clearances or approvals we obtain may be revoked if any issues arise that bring into question our products' safety or effectiveness. Any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations.

Sales of our diagnostic products outside the United States will be subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may

differ from that required to obtain FDA approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. In addition, the FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to commercialize our diagnostic products outside of the United States.

We expect to rely on third parties to conduct any future studies of our diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct the clinical studies or other studies that may be required to obtain FDA and other regulatory clearance or approval for our diagnostic products, including the HTG EdgeSeq system and related proprietary panels. Accordingly, we expect to rely on third parties, such as medical institutions and clinical investigators, and providers of NGS instrumentation, to conduct such studies and/or to provide information necessary for our submissions to regulatory authorities. Our reliance on these third parties for clinical development activities or information will reduce our control over these activities. These third-parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. Similarly, providers of NGS instrumentation may not place the same importance on our regulatory submissions as we do. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, the various procedures requires under good clinical practices, or the submission of all information required in connection with requested regulatory approvals. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our diagnostic products.

Even if we are able to obtain regulatory approval or clearance for our diagnostic products, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

If we receive regulatory approval or clearance for our diagnostic products, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as compliance with QSRs, inspections by the FDA, continued adverse event and malfunction reporting, corrections and removals reporting, registration and listing, and promotional restrictions, and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our diagnostic products and/or may be subject to fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution. In addition, we may be subject to similar regulatory compliance actions of foreign jurisdictions.

If Medicare and other third-party payors in the United States and foreign countries do not approve coverage and adequate reimbursement for our future clinical diagnostic tests enabled by our technology, the commercial success of our diagnostic products would be compromised.

We plan to develop, obtain regulatory approval for and sell clinical diagnostics products for a number of different indications. Successful commercialization of our clinical diagnostic products depends, in large part, on the availability of coverage and adequate reimbursement for testing services using our diagnostic products from third-party payors, including government insurance plans, managed care organizations and private insurance plans. There is significant uncertainty surrounding third-party coverage and reimbursement for the use of tests that incorporate new technology, such as the HTG EdgeSeq system and related applications and assays. Reimbursement rates have the potential to fluctuate depending on the region in which the testing is provided, the type of facility or treatment center at which the testing is done, and the third-party payor responsible for payment. If our customers are unable to obtain positive coverage decisions from third-party payors approving reimbursement for our tests at adequate levels, the commercial success of our products would be compromised, and our revenue would be significantly limited. Even if we do obtain favorable reimbursement for our tests, third-party payors may withdraw their coverage policies, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests, which would reduce revenue for testing services based on our technology and demand for our diagnostic products.

The American Medical Association Current Procedural Terminology (“CPT”) Editorial Panel created new CPT codes that could be used by our customers to report testing for certain large-scale multianalyte GSPs, including our diagnostic products, if approved. Effective January 1, 2015, these codes allow for uniform reporting of broad genomic testing panels using technology similar to ours. While these codes standardize reporting for these tests, coverage and payment rates for GSPs remain uncertain and we cannot guarantee that coverage and/or reimbursement for these tests will be provided in the amounts we expect, or at all. Initially, industry associations recommended that payment rates for GSPs be cross-walked to existing codes on the clinical laboratory fee schedule. On

October 27, 2014, CMS issued preliminary determinations for 29 new molecular pathology codes, including the GSPs, of gapfill rather than crosswalking as recommended by the Association for Molecular Pathology. This means that local private MACs, such as Palmetto, Novidian, Novitas and Cahaba, were instructed to determine the appropriate fee schedule amounts in the first year, and CMS calculated a national payment rate based on the median of those local fee schedule amounts in the second year. This process may make it more difficult for our customers to obtain coverage and adequate reimbursement for testing services using our diagnostic products. We cannot assure that CMS and other third-party payors will establish reimbursement rates sufficient to cover the costs incurred by our customers in using our clinical diagnostic products, if approved. On September 22, 2017, gapfill pricing was set for three CPT codes which our customers may potentially utilize to obtain reimbursement, subject to regulatory limitations, for the use of our products. CPTs 81445 and 81450, for the assessment of 5-50 genes in solid and liquid tumors, respectively, were set at $598 and $760, respectively, and remains the same as of December 31, 2017. Additionally, CPT 81455 for the assessment of 51 or more genes in solid and liquid tumors was set at $2,920.

Even if we are able to establish coverage and reimbursement codes for our clinical diagnostic products in development, we will continue to be subject to significant pricing pressure, which could harm our business, results of operations, financial condition and prospects.

Third-party payors, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services, which may include decreased coverage or reduced reimbursement. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing and payment terms, including the possible requirement of a patient co-payment for Medicare beneficiaries for laboratory tests covered by Medicare, and are subject to change at any time. Reductions in the reimbursement rate of third-party payors have occurred and may occur in the future. Reductions in the prices at which testing services based on our technology are reimbursed in the future could result in pricing pressures and have a negative impact on our revenue. In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and other federal and state healthcare laws applicable to our business and marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our operations may be, and may continue to be, directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes, false claims statutes, civil monetary penalties laws, patient data privacy and security laws, physician transparency laws and marketing compliance laws. These laws may impact, among other things, our proposed sales and marketing and education programs.

The laws that may affect our ability to operate include, but are not limited to:

- The Federal Anti-kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation, rather, if one purpose of the remuneration is to induce referrals, the Federal Anti-Kickback Statute is violated.
- The federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral. Unlike the Federal Anti-Kickback Statute, the Stark Law is a strict liability statute, meaning that all of the requirements of a Stark Law exception must be met in order to be compliant with the law.

- Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other governmental third-party payors that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money to the Federal Government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the Federal Government, which may apply to entities that provide coding and billing advice to customers; the Federal Government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute or specific intent to violate it to have committed a violation.
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, maintenance, or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. In addition, the EU has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC ("Data Protection Directive"). The Data Protection Directive will be replaced starting in May 2018 with the recently adopted European General Data Protection Regulation ("GDPR"), which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. Over time we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation, including the GDPR, in the EU countries in which we operate.
- The Federal Physician Payments Sunshine Act, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as applicable manufacturers and group purchasing organizations to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members.
- State law equivalents of each of the above federal laws, such as anti-kickback, self-referral, and false claims laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the Federal Government that otherwise restricts payments that may be made to healthcare providers; state laws that require device manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

Promotional activities for FDA-regulated products have been the subject of significant enforcement actions brought under healthcare reimbursement laws, fraud and abuse laws, and consumer protection statutes, among other theories. Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. In addition, under the Federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other health care providers, and our evaluation, reagent rental and collaborative development agreements with customers, and sales and marketing efforts could be subject to challenge under one or more of such laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to, among other things: (i) comply with the regulations of the FDA, CMS, the Department of Health and Human Services Office of Inspector General ("OIG") and other similar foreign regulatory bodies; (ii) provide true, complete and accurate information to the FDA and other similar regulatory bodies; (iii) comply with manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with collaborators and key opinion leaders, as well as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

Healthcare policy changes, including recently enacted legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 ("PAMA") was signed into law, which, among other things, significantly alters the current payment methodology under the Medicare Clinical Laboratory Fee Schedule. Under the new law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a period to be defined by future regulations. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is too early to predict the impact on reimbursement for our products in development.

Also under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS was required to publicly report payment for the tests no later than January 1, 2016. We cannot determine at this time the full impact of the new law on our business, financial condition and results of operations.

The ACA makes changes that could significantly impact the biopharmaceutical and medical device industries and clinical laboratories. For example, the ACA imposes a multifactor productivity adjustment to the reimbursement rate paid under Medicare for certain clinical diagnostic laboratory tests, which may reduce payment rates. These or any future proposed or mandated reductions in

payments may apply to some or all of the clinical laboratory tests that our diagnostics customers use our technology to deliver to Medicare beneficiaries, and may reduce demand for our diagnostic products.

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. Further, the ACA includes a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, which became effective January 1, 2013. However, the Consolidated Appropriations Act of 2016, signed into law in December 2015, includes a two-year moratorium on the medical device excise tax through December 31, 2017. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 (the "2018 Appropriations Resolution") that extended the moratorium on the medical device excise tax through December 31, 2019. Absent further legislative action, the tax will be automatically reinstated for medical device sales beginning January 1, 2020. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. However, the future of the ACA is uncertain. There have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The 2017 Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2018 Appropriations Resolution delays the implementation of certain ACA-mandated fees, including, without limitation, the medical device excise tax. Congress may consider additional legislation to repeal or repeal and replace other elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, following the passage of other legislative amendments, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, then-President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare law or policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. The full impact of the ACA, as well as other laws and reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our U.S. and foreign patent and patent application portfolio relates to our nuclease-protection-based technologies as well as to lung cancer and melanoma and DLBCL biomarker panels discovered using our nuclease-protection-based technology. We have exclusive or non-exclusive licenses to multiple U.S. and foreign patents and patent applications covering technologies that we may elect to utilize in developing diagnostic tests for use on our HTG EdgeSeq system. Those licensed patents and patent applications cover technologies related to the diagnosis of breast cancer and melanoma.

If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We cannot assure investors that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for such patents to be issued. Further, we cannot assure investors that other parties will not challenge any patents issued to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We cannot guarantee investors that we will be successful in defending challenges made against our patents. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. Furthermore, in the biotechnology field, courts frequently render opinions that may adversely affect the patentability of certain inventions or discoveries, including opinions that may adversely affect the patentability of methods for analyzing or comparing nucleic acids molecules, such as RNA or DNA.

The patent positions of companies engaged in development and commercialization of molecular diagnostic tests are particularly uncertain. Various courts, including the U.S. Supreme Court, have recently rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to molecular diagnostics. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature (for example, the relationships between gene expression levels and the likelihood of risk of recurrence of cancer) are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. Accordingly, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and licensed patents.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- We might not have been the first to make the inventions covered by each of our patents and pending patent applications.
- We might not have been the first to file patent applications for these inventions.
- Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies.
- It is possible that none of our pending patent applications will result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties.
- We may not develop additional proprietary products and technologies that are patentable.

- The patents of others may have an adverse effect on our business.
- We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not yet registered certain of our trademarks, including "HTG Edge," "HTG EdgeSeq," "VERI/O," and "qNPA," in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We may need to depend on certain technologies that are licensed to us. We would not control these technologies and any loss of our rights to them could prevent us from selling some of our products.

We have entered into several license agreements with third parties for certain licensed technologies that are, or may become relevant to the products we market, or plan to market. In addition, we may in the future elect to license third party intellectual property to further our business objectives and/or as needed for freedom to operate for our products. We do not and will not own the patents, patent applications or other intellectual property rights that are a subject of these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents, patent applications and other intellectual property rights are or will be subject to the continuation of and compliance with the terms of those licenses.

We might not be able to obtain licenses to technology or other intellectual property rights that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or multiple licenses may be needed for the same product (e.g., stacked royalties). We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In some cases, we do not or may not control the prosecution, maintenance, or filing of the patents or patent applications to which we hold licenses, or the enforcement of these patents against third parties. As a result, we cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Certain of the U.S. patent rights we own, have licensed or may license relate to technology that was developed with U.S. government grants, in which case the U.S. government has certain rights in those inventions, including, among others, march-in license rights. In addition, federal regulations impose certain domestic manufacturing requirements with respect to any products within the scope of those U.S. patent claims.

We may be involved in lawsuits to protect or enforce our patent or other proprietary rights, to determine the scope, coverage and validity of others' patent or other proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.

We may from time to time receive notices of claims of infringement and misappropriation or misuse of other parties' proprietary rights, including with respect to third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or challenges to the validity or enforceability of our patents, trademarks or other rights. Some of these claims may lead to litigation. We cannot assure investors that such actions will not be asserted or prosecuted against us or that we will prevail in any or all such actions.

Litigation may be necessary for us to enforce our patent and other proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. In addition, any litigation that may be necessary in the future could result in substantial costs, even if we were to prevail, and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and in the future have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. We have not conducted comprehensive freedom-to-operate searches to determine whether the commercialization of our products or other business activities would infringe patents issued to third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers.

Many of our employees were previously employed at other medical diagnostic companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel work product could hamper or prevent our ability to

commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our products contain third-party open source software components, and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products.

Our products contain software tools licensed by third-party authors under "open source" licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales.

Although we monitor our use of open source software to avoid subjecting our products to conditions we do not intend, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, we cannot assure investors that our processes for controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, operating results, and financial condition.

We use third-party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated, which could harm our business. In addition, any errors or defects in third-party software, or other third-party software failures could result in errors, defects or cause our products to fail, which could harm our business and be costly to correct. Many of these providers attempt to impose limitations on their liability for such errors, defects or failures, and if enforceable, we may have additional liability to our customers or third-party providers that could harm our reputation and increase our operating costs.

We will need to maintain our relationships with third-party software providers and to obtain software from such providers that do not contain any errors or defects. Any failure to do so could adversely impact our ability to deliver reliable products to our customers and could harm our results of operations.

Risks Related to Being a Public Company

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Stock Market ("Nasdaq"). The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We have performed system and process evaluation and testing of our internal controls over financial reporting to allow management to report annually on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. This has required and will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts as we continue to make this assessment and ensure maintenance of proper internal controls on an ongoing basis.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we fail to establish and maintain proper and effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements, and our ability to accurately report our financial results could be adversely affected. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the Securities and Exchange Commission ("SEC") or other regulatory authorities.

Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations.*

From time to time, the FASB, either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. For example, in May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), and subsequently issued implementation guides (collectively, the "New Revenue Standard"). The New Revenue Standard superseded nearly all previous revenue recognition guidance under GAAP and became effective for us beginning January 1, 2018. We have implemented the New Revenue Standard as of January 1, 2018 in the accompanying interim unaudited condensed statements of operations and condensed balance sheets and have reflected the new disclosure requirements in the accompanying notes to the accompanying interim unaudited condensed financial statements for the quarter ended June 30, 2018. Our inability to adopt the New Revenue Standard or any new accounting standard correctly, or to update or modify our internal controls as needed, by the mandated adoption dates could adversely affect our financial reporting obligations, corresponding regulatory compliance and/or investors' confidence in us. Also, if we were to change our critical accounting estimates, including those related to the recognition of collaboration revenue and other revenue sources, our operating results could be significantly affected.

Complying with the laws and regulations affecting public companies will increase our costs and the demands on management and could harm our operating results.

As a public company, we will continue to incur significant legal, accounting and other expenses. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq, impose numerous requirements on public companies, including requiring changes in corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to compliance with these laws and regulations. These requirements have resulted in significant legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly.

As an "emerging growth company," we have availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, enacted in April 2012, and for as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years following the completion of our initial public offering in May 2015, however, we would cease to be an "emerging growth company" before the end of that five-year period as of the following December 31, if we have more than approximately $1.0 billion in annual revenue, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year, or as of the date we issue more than $1.0 billion of

non-convertible debt over a three-year period. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Our Common Stock

If we are unable to continue to satisfy the applicable continued listing requirements of Nasdaq, our common stock could be delisted.*

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "HTGM." In order to maintain this listing, we must continue to satisfy minimum financial and other continued listing requirements and standards. There can be no assurance that we will be able to continue to comply with the applicable listing standards. If we were not able to comply with applicable listing standards, our shares of common stock would be subject to delisting. The delisting of our common stock from trading on Nasdaq may have a material adverse effect on the market for, and liquidity and price of, our common stock and impair our ability to raise capital. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by customers and employees, the loss of institutional investor interest and fewer business development opportunities. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

We expect that our stock price will fluctuate significantly.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new products, significant contracts, commercial relationships or capital commitments;
- failure to obtain or delays in obtaining product approvals or clearances from the FDA or foreign regulators;
- adverse regulatory or reimbursement announcements;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the life sciences and molecular diagnostics markets;
- manufacturing disruptions;
- any future sales of our common stock or other securities;
- any change to the composition of our board of directors, executive officers or key personnel;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from Nasdaq;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic conditions and slow or negative growth of our markets; and
- the other factors described in this report under the caption "Risk Factors – Risks Related to Our Common Stock."

The stock market in general, and market prices for the securities of health technology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against

us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

In addition, to date our common stock has generally been sporadically and thinly traded. As a consequence, the trading of relatively small quantities of our shares may disproportionately influence the price of our common stock in either direction. The price for our common stock could decline precipitously if even a moderate amount of our common stock is sold on the market without commensurate demand.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by these and subsequent sales. New investors could also gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Plan ("2014 Plan") our board of directors is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 Plan will automatically increase on January 1 of each year by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, our board of directors approved the granting of rights to eligible employees to purchase shares of our common stock pursuant to our 2014 Employee Stock Purchase Plan ("ESPP") beginning January 1, 2016. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 195,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan and ESPP each year. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

We do not intend to pay dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our debt facility, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Item 1B. Unresolved Staff Comments

None.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 5. Other Information.

On August 8, 2018, the Company entered into an amendment, effective as of July 2, 2018, to the second statement of work ("SOW Two") under its Master Assay Development, Commercialization and Manufacturing Agreement (the "Governing Agreement") with QIAGEN Manchester Limited ("QML"). SOW Two relates to a project for which HTG and QML are performing collaborative development services for what is expected to be a multi-stage project leading to the potential development and commercialization of an NGS-based companion diagnostic assay in support of one or more of the therapeutic development and commercialization programs of Bristol-Myers Squibb Company. Initial-phase investigational use only ("IUO") development activities under SOW Two are complete and the amendment of SOW Two relates to the next phase, which includes the use of the IUO assay developed in the initial-phase in a retrospective clinical trial. Successful completion of the next phase activities could lead to the use of the assay in subsequent clinical trials and potential companion diagnostic development.

The next phase development activities expected to be performed by the Company and QML under the first amendment to SOW Two are expected to be completed within the third quarter of 2018. QML will pay the Company approximately $0.5 million for work to be performed under this amendment, including project management, clinical affairs support and oversight of clinical trial by the Company and its subcontractors. In addition, the Company and QML will share in any net profits (as determined under the Governing Agreement) generated by this next phase work.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description
2.1	Asset Purchase Agreement dated January 9, 2001, as amended by and between the Registrant, NuvoGen, L.L.C., Stephen Felder and Richard Kris (incorporated by reference to Exhibit 2.1 to the Registrant's registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 12, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 12, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
4.3	Common Stock Warrant issued by the Registrant to the University of Arizona, dated March 13, 2009 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
4.4	Series E Preferred Stock Warrant issued by the Registrant to Silicon Valley Bank, dated August 22, 2014 (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
4.5	Series E Preferred Stock Warrant issued by the Registrant to Oxford Finance LLC, dated August 22, 2014 (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
4.6	Form of Warrant issued by Registrant to bridge financing investors (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
4.7	Form of Warrant issued by Registrant to bridge financing investors (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
4.8	Common Stock Warrant issued by the Registrant to Oxford Finance LLC, dated March 28, 2016 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 30, 2016).
4.9	Subordinated Convertible Promissory Note, dated October 26, 2017, by and between the Company and QIAGEN North American Holdings, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 27, 2017).
4.10	Warrant issued to MidCap Funding XXVIII Trust, dated March 26, 2018 (incorporated by reference to Exhibit 4.10 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2018).
10.1*	Statement of Work No. 3, dated January 12, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2018).
10.2	Credit and Security Agreement (Term Loan) by and among the Registrant, the lenders party thereto from time to time and MidCap Financial Trust, as agent, dated March 26, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2018).
10.3	Credit and Security Agreement (Revolving Loan) by and among the Registrant, the lenders party thereto from time to time and MidCap Funding IV Trust (assignee of MidCap Financial Trust), as agent, dated March 26, 2018 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2018).

Exhibit Number	Description
10.4*	Second Amendment to Statement of Work No. 1, dated March 30, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2018).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* We have requested confidential treatment for certain portions of this agreement. Omitted portions have been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HTG Molecular Diagnostics, Inc.

Date: August 8, 2018

By: /s/ Timothy B. Johnson

Timothy B. Johnson

Chief Executive Officer

(Principal Executive Officer)

Date: August 8, 2018

By: /s/ Shaun D. McMeans

Shaun D. McMeans

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy B. Johnson, certify that:

1. I have reviewed this Form 10-Q of HTG Molecular Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected or is reasonably likely to materially affect the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2018

By: /s/ Timothy B. Johnson

Timothy B. Johnson
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shaun D. McMeans, certify that:

1. I have reviewed this Form 10-Q of HTG Molecular Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected or is reasonably likely to materially affect the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2018

By: /s/ Shaun D. McMeans

Shaun D. McMeans
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HTG Molecular Diagnostics, Inc. (the "Company") on Form 10-Q for the quarter ending June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2018

By: /s/ Timothy B. Johnson

Timothy B. Johnson
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HTG Molecular Diagnostics, Inc. (the "Company") on Form 10-Q for the quarter ending June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2018

By: /s/ Shaun D. McMeans

Shaun D. McMeans
Chief Financial Officer
(Principal Financial and Accounting Officer)