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 September 30, 2016

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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)	Small reporting company	☒

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 November 4, 2016, the registrant had 7,065,254 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

	September 30, 2016	December 31, 2015
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 5,523,824	$ 3,293,983
Short-term investments available-for-sale, at fair value	11,097,140	28,201,507
Accounts receivable	591,861	716,246
Inventory, net of allowance of $667,553 at September 30, 2016 and $284,319 at December 31, 2015	1,867,685	2,201,301
Prepaid insurance	215,236	234,777
Prepaid expenses and other	226,070	210,440
Total current assets	19,521,816	34,858,254
Long-term investments available-for-sale, at fair value	—	2,603,901
Property and equipment, net	3,666,947	1,932,213
Total assets	$ 23,188,763	$ 39,394,368
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,117,830	$ 724,805
Accrued liabilities	1,292,285	1,915,268
Deferred revenue	283,663	47,476
NuvoGen obligation	582,614	543,750
Term loan	6,254,688	3,059,068
Other current liabilities	270,041	29,243
Total current liabilities	9,801,121	6,319,610
Term loan payable - non-current, net of discount and debt issuance costs	6,902,379	7,737,586
NuvoGen obligation - non-current, net of discount	8,169,861	8,415,122
Other	530,159	28,652
Total liabilities	25,403,520	22,500,970
Commitments and Contingencies		
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2016 and December 31, 2015, 7,060,269 and 7,058,873 shares issued and outstanding, respectively, at September 30, 2016, 6,845,638 and 6,844,242 shares issued and outstanding, respectively, at December 31, 2015	7,059	6,844
Additional paid-in-capital	107,786,467	106,569,405
Treasury stock – 1,396 shares, at cost	(75,000)	(75,000)
Accumulated other comprehensive loss	(320)	(41,357)
Accumulated deficit	(109,932,963)	(89,566,494)
Total stockholders' equity (deficit)	(2,214,757)	16,893,398
Total liabilities and stockholders' equity (deficit)	$ 23,188,763	$ 39,394,368

See notes to the unaudited condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Product	$ 506,065	$ 973,956	$ 1,683,382	$ 2,349,740
Service	407,836	37,000	1,991,567	150,292
Other	—	—	—	325,789
Total revenue	913,901	1,010,956	3,674,949	2,825,821
Cost of revenue	1,125,009	809,015	2,901,455	2,538,590
Gross margin	(211,108)	201,941	773,494	287,231
Operating expenses:				
Selling, general and administrative	3,937,600	3,717,402	13,343,945	10,883,161
Research and development	1,910,116	1,309,573	6,515,808	2,951,009
Total operating expenses	5,847,716	5,026,975	19,859,753	13,834,170
Operating loss	(6,058,824)	(4,825,034)	(19,086,259)	(13,546,939)
Other income (expense):				
Loss from change in stock warrant valuation	—	—	—	(239,683)
Interest expense	(490,825)	(378,656)	(1,422,171)	(1,334,103)
Interest income	26,196	37,788	92,767	48,930
Loss on settlement of convertible debt	—	—	—	(705,217)
Other	35,011	8,239	53,453	78,873
Total other income (expense)	(429,618)	(332,629)	(1,275,951)	(2,151,200)
Net loss before income taxes	(6,488,442)	(5,157,663)	(20,362,210)	(15,698,139)
Income taxes	—	—	4,259	—
Net loss	(6,488,442)	(5,157,663)	(20,366,469)	(15,698,139)
Accretion of stock issuance costs	—	—	—	(35,046)
Accretion of Series E warrant discount	—	—	—	(127,616)
Accretion of Series D and E redeemable convertible preferred stock dividends	—	—	—	(1,165,932)
Net loss attributable to common stockholders	$ (6,488,442)	$ (5,157,663)	$ (20,366,469)	$ (17,026,733)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.92)	$ (0.76)	$ (2.92)	$ (4.56)
Shares used in computing net loss per share attributable to common stockholders, basic and diluted	7,053,010	6,829,687	6,985,924	3,735,852

See notes to the unaudited condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (6,488,442)	$ (5,157,663)	$ (20,366,469)	$ (15,698,139)
Other comprehensive income (loss), net of tax effect:				
Unrealized gain (loss) on short and long-term investments	(2,836)	12,993	41,037	4,754
Comprehensive loss	(6,491,278)	(5,144,670)	(20,325,432)	(15,693,385)
Less: Accretion of stock issuance costs	—	—	—	(35,046)
Less: Accretion of Series E warrant discount	—	—	—	(127,616)
Less: Accretion of Series D and E redeemable convertible preferred stock dividends	—	—	—	(1,165,932)
Comprehensive loss attributable to common stockholders	$ (6,491,278)	$ (5,144,670)	$ (20,325,432)	$ (17,021,979)

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	Treasury	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Stock	Loss	Deficit	(Deficit)
Balance at January 1, 2016	6,844,242	$ 6,844	$106,569,405	$ (75,000)	$ (41,357)	$ (89,566,494)	$ 16,893,398
Stock issued for payment of 2015 annual bonus	133,179	133	364,777	—	—	—	364,910
Exercise of stock options	4,712	5	10,127	—	—	—	10,132
Stock-based compensation expense	36,762	37	552,017	—	—	—	552,054
Employee stock purchase plan purchases	39,978	40	167,681	—	—	—	167,721
Growth Term Loan B warrant discount	—	—	122,460	—	—	—	122,460
Net loss	—	—	—	—	—	(20,366,469)	(20,366,469)
Other comprehensive income	—	—	—	—	41,037	—	41,037
Balance at September 30, 2016	7,058,873	$ 7,059	$107,786,467	$ (75,000)	$ (320)	$(109,932,963)	$ (2,214,757)

See notes to the unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$ (20,366,469)	$ (15,698,139)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,086,752	473,799
Accretion of discount on NuvoGen obligation	156,103	229,232
Bad debt expense, net of recoveries	—	44,854
Provision for excess inventory	437,893	273,752
Amortization of Growth Term Loan discount and issuance costs	415,355	274,486
Loss on settlement of convertible notes	—	705,217
Amortization of discount on convertible notes	—	90,222
Stock-based compensation expense	552,054	223,787
Change in redeemable convertible preferred stock warrant liability	—	239,683
Accretion of incentive from landlord	(94,667)	—
Accrued interest on available-for-sale securities investments	130,576	—
Loss on disposal of assets	—	67,780
Changes in operating assets and liabilities:		
Accounts receivable	124,385	59,444
Inventory	(104,277)	(854,120)
Prepaid expenses and other	3,911	(505,918)
Accounts payable	367,529	(254,423)
Accrued liabilities	(258,073)	(47,367)
Deferred revenue	236,187	(8,532)
Net cash used in operating activities	(17,312,741)	(14,686,243)
Investing activities		
Purchase of property and equipment	(1,859,155)	(950,278)
Sales, redemptions and maturities of available-for-sale securities	23,000,000	—
Purchase of available-for-sale securities	(3,381,271)	(36,473,957)
Net cash provided by (used in) investing activities	17,759,574	(37,424,235)
Financing activities		
Proceeds from initial public offering	—	47,654,190
Deferred offering costs	—	(1,002,930)
Proceeds from Growth Term Loan	5,000,000	—
Payments on Growth Term Loan	(2,932,482)	—
Proceeds from convertible notes	—	4,500,000
Deferred convertible note financing costs	—	(75,523)
Payments on capital leases	(99,863)	(21,933)
Proceeds from exercise of stock options	10,132	34,048
Proceeds from exercise of Series E warrants	—	8,948
Proceeds from issuance of convertible note warrants	—	1,354
Proceeds from shares purchased under the stock purchase plan	167,721	—
Payments on NuvoGen obligation	(362,500)	—
Settlement of fractional common shares	—	(2,925)
Net cash provided by financing activities	1,783,008	51,095,229
Increase (decrease) in cash and cash equivalents	2,229,841	(1,015,249)
Cash and cash equivalents at beginning of period	3,293,983	3,613,392
Cash and cash equivalents at end of period	$ 5,523,824	$ 2,598,143
Noncash investing and financing activities		
Accretion of preferred stock issuance costs	$ —	$ 35,046
Net exercise of Series D and Series E warrants	—	(95,914)
Accretion of Series E warrant discount	—	127,616
Accretion of Series D and Series E redeemable convertible preferred stock dividends	—	1,165,932
Deferred offering costs reclassified to distributions in excess of capital	—	2,297,079
Allocation of Series E warrant convertible notes debt discount	—	741,828
Conversion of convertible notes and related accrued interest to common stock	—	4,544,384
Conversion of convertible preferred stock to common stock	—	(57,356,049)
Reclassification of convertible preferred stock liability warrants to equity warrants	—	(1,616,140)
Fixed asset purchases payable and accrued at period end	25,496	272,847
Stock issued for settlement of accrued bonus	(364,910)	—
Purchase of property and equipment under capital lease	226,835	—
Incentive from landlord	710,000	—
Supplemental cash flow information		
Cash paid for interest	$ 850,713	$ 701,250

See notes to the unaudited condensed financial statements.

Note 1. Description of Business

HTG Molecular Diagnostics, Inc. (the "Company") is a commercial stage company that develops and markets a novel technology platform to facilitate the routine use of complex molecular profiling. The Company's HTG Edge and HTG EdgeSeq platforms, consisting of instrumentation, consumables and software analytics, are used in sample profiling applications including tumor profiling, molecular diagnostic testing and biomarker development. The Company's HTG Edge and HTG EdgeSeq platforms automate the molecular profiling of genes and gene activity using its proprietary nuclease protection chemistry on a wide variety of biological samples. The Company derives revenue from the sale of instruments, consumables and related services.

The Company operates in one segment and its customers are primarily located in the United States. For the three and nine months ended September 30, 2016, approximately 15% and 11%, respectively, of the Company's revenue was generated from sales to customers located outside of the United States, compared with 24% and 11%, respectively, for the three and nine months ended September 30, 2015.

Note 2. Basis of Presentation

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 (the "SEC") and reflect the accounts of the Company as of September 30, 2016. 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 unaudited condensed balance sheet at December 31, 2015 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 financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the fiscal year ended December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the SEC on March 24, 2016.

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.

Going Concern

The Company implemented the criteria of Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, in the first quarter of 2016. In accordance with this guidance, management has assessed the Company's ability to continue as a going concern within one year of the filing date of this Quarterly Report on Form 10-Q with the SEC. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, the Company has had recurring operating losses and negative cash flows from operations since its inception and has an accumulated deficit of approximately $109.9 million. As of September 30, 2016, the Company had available cash, cash equivalents and investments in short term available-for-sale securities of approximately $16.6 million, and had current liabilities of approximately $10.0 million plus an additional $6.9 million in long-term liabilities attributable to its growth term loan. Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations and expenditures until mid-way through the second quarter of 2017. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that may result from the outcome of these uncertainties.

The Company will need to raise additional capital to fund its operations until its revenue reaches a level sufficient to provide for self-sustaining cash flows. There can be no assurance that additional capital will be available on acceptable terms, or that the Company's revenue will reach a level sufficient to provide for self-sustaining cash flows. If sufficient additional capital is not available as and when needed, the Company may have to delay, scale back or discontinue one or more product development programs, curtail its 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 independently, cease operations altogether, pursue an acquisition of the Company at a price that may result in up to a total loss on investment for its stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all assets.

Change in Accounting Principle

In April 2015, the Financial Accounting Standards Board ("FASB") issued ASU No. 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). The standard requires entities to present debt issuance costs on the balance sheet as a direct deduction from the related debt liability rather than as an asset, and to report amortization as interest expense. The requirements were to be applied on a retrospective basis. The Company adopted ASU 2015-03 effective January 1, 2016. As such, prepaid expenses and other and term loan payable – non-current, net of discount have been restated as of December 31, 2015 to reflect the retrospective reclassification of $52,377 of Growth Term Loan deferred financing fees from prepaid expenses and other to term loan payable – non-current, net of discount and debt issuance costs.

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, the value of the warrant liability, the resolution of uncertain tax positions, income tax valuation allowances, recovery of long-lived assets, inventory obsolescence and inventory valuation. Actual results could materially differ from those estimates.

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 instruments, consumables, sample processing services, custom panel design services and contract research 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 had product revenue consisting of revenue from the sale of instruments and consumables for the three and nine months ended September 30, 2016 and 2015 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Instruments	$ 5,846	$ 338,231	$ 88,146	$ 597,426
Consumables	500,219	635,725	1,595,236	1,752,314
Total product sales	$ 506,065	$ 973,956	$ 1,683,382	$ 2,349,740

The Company's top three customers accounted for 27%, 24% and 9% of the Company's revenue for the three months ended September 30, 2016, compared with 26%, 16% and 12% for the three months ended September 30, 2015. The top three customers accounted for 38%, 14% and 7% of the Company's revenue for the nine months ended September 30, 2016, compared with 29%, 10% and 6% of the Company's revenue for the nine months ended September 30, 2015.

The top two customers accounted for approximately 59% and 11% of the Company's net accounts receivable as of September 30, 2016, compared with approximately 32% and 25% as of December 31, 2015.

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

Recent Accounting Pronouncements

In May 2014, the FASB issued 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 are required under existing GAAP.

The revised revenue standard is 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 is currently evaluating the impact of the pending adoption of ASU 2014-09 on its financial statements and has not yet determined the method by which it will adopt the standard.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory: Simplifying the Measurement of Inventory*. The standard requires inventory within the scope of the ASU to be measured using the lower of cost and net realizable value. The changes apply to all types of inventory, except those measured using last in, first out ("LIFO") or retail inventory method, and are intended to more clearly articulate the requirements for the measurement and disclosure of inventory and to simplify the accounting for inventory by eliminating the concepts of replacement cost and net realizable value less a normal profit margin. The standard will be effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2016. The Company does not believe the adoption of this standard will have a significant impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. Under this standard, lessees will be required to recognize for all leases (with the exception of short-term leases) a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and 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 Company is currently evaluating the effect that the adoption of this standard will have on its financial statements.

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. ASU 2016-08 will be effective for public entities for fiscal years and interim periods within those fiscal years beginning after December 15, 2017. In addition, entities are required to adopt ASU 2016-08 by using the same transition method they used to adopt ASU 2014-09. The Company is currently evaluating the effect the adoption of ASU 2016-08 will have on its financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Share-Based Payment: Simplifying the Accounting for Share-Based Payments*. The standard addresses several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. The new standard will be effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2016. The Company does not believe the adoption of this standard will have a significant impact on its financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"). The amendments in this standard affect the guidance in ASU 2014-09 by clarifying two aspects: identifying performance obligations and the licensing implementation guidance. ASU 2016-10 will have the same effective date and transition requirements as ASU 2014-09. The Company is currently evaluating the effect the adoption of ASU 2016-10 will have on its financial statements.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow Scope Improvements and Practical Expedients* ("ASU 2016-12"). 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. ASU 2016-12 will have the same effective date and transition requirements as ASU 2014-09. The Company is currently evaluating the effect the adoption of ASU 2016-12 will have on its financial statements.

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 held at the reporting date based on historical experience, current conditions and reasonable forecasts. 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 will be 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.

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. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years with early adoption permitted, including adoption in an interim period. The Company is currently evaluating the effect that the adoption of ASU 2016-15 will have on its financial statements.

Note 3. Inventory

HTG Edge or HTG EdgeSeq instruments at customer locations under evaluation agreements are included in finished goods inventory. Equipment that is under evaluation for purchase remains in inventory as the Company retains title to the equipment throughout the evaluation period. The period of time customers use to evaluate the Company's equipment generally ranges from 90 to 180 days, and in certain circumstances the evaluation period may be extended beyond 180 days. If the customer has not completed the purchase of the instrument by the end of the initial evaluation period, the Company will determine whether to extend the evaluation period or have the equipment returned to the Company. If the customer has not purchased the equipment or entered into a reagent agreement with the Company within one year, the equipment is returned to the Company or the customer is allowed to continue use of the equipment in which case the cost of the equipment is written off to selling, general and administrative expense.

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

	September 30, 2016	December 31, 2015
Raw materials	$ 1,584,273	$ 1,274,840
Work in process	1,991	—
Finished goods	948,974	1,210,780
Total gross inventory	2,535,238	2,485,620
Less inventory allowance	(667,553)	(284,319)
	$ 1,867,685	$ 2,201,301

For the three and nine months ended September 30, 2016, the Company recorded adjustments to provision for excess inventory $288,130 and $437,893, respectively, resulting in a net adjustment to inventory allowance of $291,692 and $383,234, respectively. For the three and nine months ended September 30, 2015, the Company recorded adjustments to provision for excess inventory of $76,799 and $330,088, respectively, resulting in a net adjustment to the inventory allowance of $62,872 and $273,752, respectively. Adjustments in these periods to the allowance for estimated shrinkage and obsolescence and excess inventory were recognized within cost of revenue in the condensed statements of operations. During the nine months ended September 30, 2016 and 2015, the Company wrote off $54,659 and $56,336, respectively, of obsolete inventory against the inventory allowance.

Note 4. Fair Value 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 dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The Company's portfolio of available-for-sale securities comprises U.S. Treasuries, U.S. government sponsored agency obligations and high credit quality corporate debt securities.

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 September 30, 2016 and December 31, 2015, respectively in the fair value hierarchy:

	Balance at September 30, 2016			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 4,897,198	$ —	$ —	$ 4,897,198
Investments available-for-sale at fair value				
U.S. government obligations	$ 1,302,991	$ —	$ —	$ 1,302,991
U.S. government agency obligations	$ —	$ 3,582,980	$ —	$ 3,582,980
Corporate debt securities	$ —	$ 6,211,169	$ —	$ 6,211,169

	Balance at December 31, 2015			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 3,290,490	$ —	$ —	$ 3,290,490
Investments available-for-sale at fair value				
U.S. government obligations	$ 3,298,014	$ —	$ —	$ 3,298,014
U.S. government agency obligations	$ —	$ 14,589,378	$ —	$ 14,589,378
Corporate debt securities	$ —	$ 12,918,016	$ —	$ 12,918,016

There are no other financial instruments subject to fair value measurement on a recurring basis. Transfers to/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 nine months ended September 30, 2016 or 2015.

Level 1 instruments include investments in money market funds and U.S. Treasuries. 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 U.S. Government agency obligations and 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 periods ended September 30, 2016 or December 31, 2015.

Note 5. Available for Sale Securities

The following is a summary of the Company's available-for-sale securities at September 30, 2016 and December 31, 2015:

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
U.S. Treasury securities and obligations of U.S. government agencies	$ 4,884,459	$ 1,511	$ —	$ 4,885,970
Corporate debt securities	6,213,001	$ —	(1,831)	6,211,170
Total available-for-sale securities	$ 11,097,460	$ 1,511	$ (1,831)	$ 11,097,140

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
U.S. Treasury securities and obligations of U.S. government agencies	$ 17,914,136	$ —	$ (26,744)	$ 17,887,392
Corporate debt securities	12,932,629	397	(15,010)	12,918,016
Total available-for-sale securities	$ 30,846,765	$ 397	$ (41,754)	$ 30,805,408

The net adjustment to unrealized holding gains (losses) on available-for-sale securities in other comprehensive income totaled $(2,836) and $41,037 for the three and nine months ended September 30, 2016, respectively, and $12,993 and $4,754 for the three and nine months ended September 30, 2015, respectively.

Contractual maturities of debt investment securities at September 30, 2016 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 and obligations of U.S. government agencies	$ 4,885,970	$ —	$ 4,885,970
Corporate debt securities	6,211,170	—	6,211,170
Total available-for-sale securities	$ 11,097,140	$ —	$ 11,097,140

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 September 30, 2016:

	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 and obligations of U.S. government agencies	$ —	$ —	$ —	$ —	$ —	$ —
Corporate debt securities	2,817,800	(1,831)	—	—	2,817,800	(1,831)
Total available-for-sale securities with unrealized losses	$ 2,817,800	$ (1,831)	$ —	$ —	$ 2,817,800	$ (1,831)

For debt securities, management 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. If so, any impairment would be recognized through earnings. 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, 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 and market conditions. The Company did not have any other-than-temporary impairment in its debt securities for the three and nine months ended September 30, 2016.

Note 6. Property and Equipment

Property and equipment, net, consists of the following:

	September 30, 2016	December 31, 2015
Office equipment	$ 499,362	$ 257,296
Leasehold improvements	1,847,378	224,061
Laboratory and manufacturing equipment	3,445,446	2,442,191
Field equipment	131,096	180,355
Software	140,248	140,248
Construction in progress	145,063	175,501
	6,208,593	3,419,652
Less: accumulated depreciation and amortization	(2,541,646)	(1,487,439)
	$ 3,666,947	$ 1,932,213

Depreciation and leasehold improvement amortization expense was $357,924 and $1,086,752 for the three and nine months ended September 30, 2016, respectively, and $174,390 and $473,799 for the three and nine months ended September 30, 2015, respectively.

At September 30, 2016, the total cost and accumulated amortization of assets under lease commitments were $373,048 and $188,179, respectively, while cost and accumulated depreciation at December 31, 2015 were $146,213 and $88,220, respectively. Leased asset amortization has been included in depreciation and amortization expense within the condensed statements of operations for the three and nine months ended September 30, 2016 and 2015.

During the first quarter of 2016, the Company capitalized landlord funded lease incentives as leasehold improvements to be amortized over the shorter of the useful life or the remaining life of the real estate lease (see Note 14).

Note 7. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2016	December 31, 2015
Employee compensation and benefits	$ 756,501	$ 1,240,314
Employee compensation for future absences	160,183	154,107
Interest	93,413	77,917
Professional fees	63,480	140,385
Other	218,708	302,545
	$ 1,292,285	$ 1,915,268

Note 8. Debt Obligations

Growth Term Loan

In August 2014, the Company entered into a Loan and Security Agreement (the "Growth Term Loan") with a syndicate of two lending institutions, Oxford Finance LLC and Silicon Valley Bank, which was amended in August 2015 and June 2016. The first tranche of the Growth Term Loan ("Growth Term Loan A") of $11.0 million was funded in August 2014. The second tranche of $5.0 million ("Growth Term Loan B") was funded in March 2016. The August 2015 amendment extended the monthly interest-only payment period until April 1, 2016. Following the interest-only payment period, the Company became obligated to make equal monthly payments of principal and interest amortized over the remaining term of the loan for all funds drawn under Growth Term Loan A and B. Growth Term Loan A and B bear interest at the fixed rates of 8.5% and 8.75%, respectively and mature in September 2018. Should a prepayment be made, the Company will be obligated to pay a prepayment fee equal to (i) 3% of the principal amount prepaid if the growth term loan is prepaid on or before the first anniversary of the August 2015 amendment, (ii) 2% of the principal amount repaid if the growth term loan is prepaid after the first anniversary but on or prior to the second anniversary of the August 2015 amendment and (iii) 1% of the principal amount repaid if the growth term loan is repaid after the second anniversary of the August 2015 amendment and prior to maturity. The amendment also increased the final payment percentage to 4.75%. The June 2016 amendment modified the definitions of permitted indebtedness and permitted liens to provide for an increased maximum amount of permitted indebtedness, authorize a new category of permitted indebtedness and authorize a new category of permitted liens. The Growth Term Loan requires

the Company to maintain compliance with specific reporting covenants and does not require financial covenants. The Growth Term Loan is secured by a lien covering substantially all of the Company's assets, excluding patents, trademarks and other intellectual property rights (except for rights to payment related to the sale, licensing or disposition of such intellectual property rights) and certain other specified property.

The Company received the Growth Term Loan A proceeds net of a $0.3 million original issue discount. The Company also recorded a discount for the issuance of warrants with the Growth Term Loan A. The original issuance discount and warrant discount are being amortized, using the effective interest method, over the term of the Growth Term Loan A. Amortization expense was $46,727 and $148,859 for the three and nine months ended September 30, 2016, respectively, and $31,595 and $120,627 for the three and nine months ended September 2015, respectively, and is included in interest expense in the accompanying condensed statements of operations. The Company has recorded approximately $31,067 and $52,377 of deferred financing costs net of the related debt in the accompanying condensed balance sheets as of September 30, 2016 and December 31, 2015, respectively, in accordance with ASU 2015-03, which was adopted on January 1, 2016. Deferred financing cost amortization expense was $6,689 and $21,310 and $4,523 and $22,353 for the three and nine months ended September 30, 2016 and 2015, respectively, and is included in interest expense in the accompanying condensed statements of operations. In addition, in connection with the Growth Term Loan A, the Company issued preferred stock warrants to the lenders exercisable for 2,512,562 shares of Series E redeemable convertible preferred stock ("Series E Stock") at a price of $0.2189 per share. Upon completion of the Company's IPO in May 2015, the warrants were automatically converted to common stock warrants exercisable for up to 23,396 shares of common stock at an exercise price of $23.51 per share. The warrants expire on August 22, 2024.

The final fee premium relating to the Growth Term Loan B of $237,500 is being amortized to interest expense, using the effective interest method, over the term of the Growth Term Loan B. In connection with the funding of the Growth Term Loan B, in March 2016, the Company issued Oxford Finance LLC a common stock warrant exercisable for 45,307 shares of common stock at an exercise price of $2.759 per share, and the warrant issued to Silicon Valley Bank automatically became exercisable for an additional 5,317 shares of common stock at an exercise price of $23.51 per share in accordance with the terms of the Growth Term Loan. The fair value of the discount of $122,460, was calculated using the Black-Scholes option pricing model at March 31, 2016. The warrant discount is being amortized to interest expense, using the effective interest method, over the term of the Growth Term Loan B. Amortization for the three and nine months ended September 30, 2016 was $18,918 and $40,838, respectively. There was no amortization for the three and nine months ended September 30, 2015 on Growth Term Loan B discount because the Growth Term Loan B was not outstanding during those periods.

The principal repayments due under the term loan as of September 30, 2016, are as follows:

2016	$ 1,513,915
2017	6,389,782
2018	5,163,822
Total Growth Term Loan payments	13,067,519
Less discount and deferred financing costs	(329,708)
Plus final fee premium	419,256
Total Growth Term Loan, net	$ 13,157,067

Convertible Notes

On December 30, 2014, the Company entered into two, separate subordinated convertible promissory note agreements (the "Note Agreements"). The Note Agreements provided that upon a qualified equity financing, pursuant to which the Company raised either through a qualified IPO of common stock or through a qualifying private placement of convertible preferred stock, gross offering proceeds of at least $20,000,000 from the sale of shares to new investors, the outstanding principal amount and all accrued but unpaid interest under convertible notes issued pursuant to the Note Agreements would automatically convert into shares of common stock or preferred stock, whichever was sold in the offering. The number of shares into which the convertible notes were convertible was equal to the outstanding principal and accrued interest divided by the price per share paid by investors purchasing such newly issued equity securities.

Draws under the first Note Agreement in February, March and April 2015 totaled $4.5 million. There were no draws under the second Note Agreement prior to the Company's IPO in May 2015. The Company recorded a $741,828 discount for the estimated fair value of warrants issued in connection with the debt. Amortization of the Note Agreement discount and deferred financing fees associated with the Note Agreements was $0 and $90,222 for the three and nine months ended September 30, 2015, respectively, which was included in interest expense in the accompanying condensed statements of operations.

Settlement of Convertible Debt upon IPO Closing

Upon the initial closing of the Company's IPO in May 2015, all outstanding principal and accrued interest was settled by issuing 324,591 shares of common stock valued at the IPO price of $14.00 for a total of $4.5 million. The Company evaluated the terms of the Note Agreements at inception and concluded that the convertible notes issued thereunder should be accounted for as share settled debt as they fall within the scope of ASC Topic 480, *Distinguishing Liabilities from Equity*. While the debt issued under the Note Agreements contains multiple events that could trigger settlement at different values, the Company evaluated all of the possible outcomes and considered the qualified IPO outcome to be predominant at more than 50 %. The IPO settlement triggering event settles the fixed monetary amount of the debt known at inception with a variable number of shares of common stock based on the price of the common stock at settlement and therefore meets the definition of share settled debt. The Company compared the value of the common stock issued to settle the debt with the carrying amount of the debt at the IPO closing date of May 2015, net of unamortized discount and deferred financing costs, and recorded a loss on settlement of debt of $0 and $705,217 in the accompanying condensed statement of operations for the three and nine months ended September 30, 2015, respectively. The value of the debt adjusted to the value of the common stock paid was reclassified from debt to equity. No such loss on settlement of debt was recorded for either the three and nine months ended September 30, 2016.

Note 9. Other Agreements

NuvoGen Obligation

The Company entered into an asset purchase agreement in 2001, as amended, with NuvoGen Research, LLC ("NuvoGen") to acquire certain intellectual property from NuvoGen. The Company accounted for the transaction as an asset acquisition. However, as the intellectual property was determined to not have an alternative future use, the upfront consideration was expensed. In exchange for the intellectual property, the Company issued to NuvoGen 5,587 shares of the Company's common stock, made fixed payments of $740,000 over the first two years of the agreement and agreed to pay NuvoGen 6% of the Company's yearly revenue, which would be applied to any fixed payments, until the total aggregate cash compensation paid to NuvoGen under the agreement equaled $15,000,000. Certain terms of the agreement were amended in November 2003, September 2004, November 2012 and February 2014. Pursuant to the latest amendment to the agreement, through 2017, the Company is only required to pay a yearly fixed fee, in quarterly installments, to NuvoGen in the range of $543,750 to $800,000, and may defer any accrued revenue-based payments. Beginning in 2018, the Company will be obligated to pay the greater of $400,000 or 6% of the Company's applicable annual revenues, plus amounts, if any, deferred in the 2016 and 2017 periods by which 6% of revenue exceeds the applicable fixed fee plus 5% interest on such deferred amounts until the obligation is paid in full. The obligation currently is non-interest bearing and was, but is no longer, secured by certain patents and trademarks.

The Company recorded the obligation at the estimated present value of the future payments using a discount rate of 2.5%, the Company's estimate of its effective borrowing rate for similar obligations. Unamortized debt discount was $127,518 and $283,621 at September 30, 2016 and December 31, 2015, respectively. Discount accreted during the three and nine months ended September 30, 2016 was $51,636 and $156,103, respectively, and $51,481 and $229,232, during the three and nine months ended September 30, 2015, respectively.

Pursuant to the closing of the Growth Term Loan A in August 2014 (see Note 8), the Company agreed to accelerate certain minimum payments pursuant to the asset purchase agreement and NuvoGen agreed to terminate its security interest in the originally pledged patents and trademarks. Remaining minimum payments that were otherwise due for 2014, 2015 and the first quarter of 2016, amounting to $868,750 were paid in advance. The acceleration of payments did not significantly change the minimum cash flows and therefore had no significant accounting effect. Since quarterly payments resumed in the second quarter of 2016, $362,500 has been paid to NuvoGen toward the remaining obligation.

The remaining payments due to NuvoGen at September 30, 2016, are, minimally, as follows, although actual payments could be significantly more than provided in the table in 2018 and beyond to the extent that 6% of revenue exceeds $400,000:

2016	$ 181,250
2017	800,000
2018	400,000
2019	400,000
2020	400,000
2021 and beyond	6,698,743
Total NuvoGen obligation payments	8,879,993
Less discount	(127,518)
Total NuvoGen obligation, net	$ 8,752,475

Illumina, Inc. Agreement

In October 2014, the Company entered into a development and component supply agreement with Illumina, Inc. for the development and worldwide commercialization by the Company of up to two complete diagnostic gene expression profiling tests for use with Illumina's diagnostic instruments, using components supplied by Illumina. The Company refers to these diagnostic gene expression profiling tests as in vitro diagnostic ("IVD") test kits. The IVD test kits originally could be used in up to two discrete testing fields chosen by the Company, one or both of which could relate to oncology for breast, lung, lymphoma or melanoma tumors, and up to one of which could relate to transplant, chronic obstructive pulmonary disease, or immunology/autoimmunity. The Company provided notice to Illumina of its first testing selection during the quarter ended March 31, 2015. The Company is in discussions with Illumina regarding a potential extension of the original October 2016 deadline to select a second field.

In the fourth quarter of 2015, the Company and Illumina agreed to a development plan for the development and regulatory approval of the selected IVD test kit, following which the Company paid Illumina a $100,000 fee. Illumina has agreed to provide development and regulatory support as part of the plan. The Company is also required to pay Illumina up to $1.0 million in the aggregate upon achievement of specified regulatory milestones relating to the IVD test kit, though no additional milestones have been reached through September 30, 2016. In addition, the Company has agreed to pay Illumina a single digit percentage royalty on net sales of any IVD test kit that the Company commercializes pursuant to the agreement. Ongoing research and development costs for these programs have been expensed as incurred.

The agreement will expire on the earlier of October 2019 or the date which the last to expire development plan under the agreement is completed. The Company may terminate the agreement at any time upon 90 days' written notice and may terminate any development plan under the agreement upon 30 days' prior written notice. Illumina may terminate the agreement upon 30 days' prior written notice if the Company undergoes certain changes of control. Either party may terminate the agreement upon the other party's material breach of the agreement that remains uncured for 30 days, or upon the other party's bankruptcy

Invetech PTY Ltd. Agreement

In September 2015, the Company entered into a development and professional services agreement with Invetech PTY Ltd. ("Invetech"), for the conduct of research and development of a next generation automated sample library preparation instrument. This instrument is to be a low volume throughput version of the Company's existing HTG EdgeSeq system technology and is being referred to as Project JANUS.

The agreement requires the execution of a development plan for each stage of the project. Upon full execution and delivery of each development plan, the Company will pay Invetech development fee installments for that development plan. Stage 0 was completed during the second half of 2015. In July 2016, the Company entered into an amendment with Invetech, extending and concluding Stage 1.1 through the end of July 2016 and further suspending Invetech's project development activities currently in process until the Company makes a decision to resume further external development efforts. Resumption of the external development effort is not expected until 2017 and will depend upon the prioritization of all of the Company's development programs. The Invetech agreement remains in effect through completion of all tasks and the Company's acceptance of all deliverables under each development plan unless terminated earlier as provided for in the agreement.

Research and development expense included in the condensed statements of operations relating to Invetech development fee installments was $287,100 and $2,310,758 for the three and nine months ended September 30, 2016, respectively, and $150,000 for both the three and nine months ended September 30, 2015.

Life Technologies Corporation Agreement

In March 2016, the Company entered into an Authorization, Supply and Regulatory Authorization Agreement with Life Technologies Corporation ("LTC"), a wholly owned subsidiary of Thermo Fisher Scientific, Inc., for the development and worldwide commercialization by the Company of up to five RNA-based next generation sequencing panels ("HTG Assays") for use with LTC's sequencing instruments and components supplied to end-users by LTC.

Pursuant to the agreement, the Company has agreed to obtain its requirements for certain components to be used in the development of HTG Assays from LTC. In March 2016, the Company purchased approximately $250,000 of LTC products and equipment in accordance with this agreement. LTC has agreed to provide support in the Company's efforts to obtain regulatory approval of the HTG Assays. The Company is required to pay LTC a milestone payment in the mid-six figure dollar range upon certain regulatory achievements for each HTG Assay. In addition, the Company has agreed to pay LTC a single digit percentage royalty on net sales of any HTG Assays that the Company commercializes pursuant to the agreement. No milestone or royalty payments have been accrued or made pursuant to this agreement as of September 30, 2016.

Absent early termination, the initial term of the agreement will expire in March 2021 and thereafter will automatically renew for additional two year terms for as long as the Company continues to develop or sell HTG Assays. Either party may terminate the agreement by written notice delivered to the other party at least 60 days prior to the expiration of any then-current term. Either party may also terminate the agreement (a) upon the other party's material breach that remains uncured for 30 days, (b) upon the other party's bankruptcy or (c) upon written notice in the event the party providing notice reasonably determines that continued performance under the agreement would violate any regulatory law, or any other applicable law or regulation or U.S. Food and Drug Administration ("FDA") guidance.

Bristol-Myers Squibb Agreement

In May 2016, the Company entered into a Collaboration Agreement with Bristol-Myers Squibb ("BMS") for the development, in collaboration with BMS, of two custom assays based on the Company's HTG EdgeSeq technology. Following development of each custom assay, at BMS's request, the Company may also perform sample processing services using such custom assay(s) and/or supply the custom assay(s) to BMS or its third-party subcontractors. Additional custom assay development 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, and has agreed to pay an annual non-refundable, non-creditable project management fee in quarterly installments, as well as a fee for each custom assay developed. Each such fee was or is in the low six-figure range. At BMS's request, custom assay kits will be supplied and sample processing services will be performed by the Company.

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 (either a "Default") and such Default remains uncured for 60 days or such longer period if the Default cannot be cured within 60 days. BMS may terminate a project upon 90 days' prior written notice to the Company.

The agreement is a multiple-element arrangement under ASC 605-25, *Revenue Recognition – Multiple-Element Arrangements*. Custom assay development services, custom kit sales and sample processing services were each designated as an option to purchase additional products or services as described under ASC 605-25, and, as such, will not be considered in the initial allocation of contract consideration based on relative selling prices.

Each custom assay development service has three phases and each phase comprises multiple deliverables. Completion of all three phases is required for BMS to derive benefit from the respective deliverables; therefore, the three phases of a custom assay's development will be combined as one unit of accounting for revenue recognition purposes.

Under ASC 605-25, fixed and determinable contract consideration is allocated to the deliverables with stand-alone value, and revenue is recognized for each such deliverable according to the method appropriate for each deliverable. All of the fixed and determinable contract consideration will be allocated to one deliverable, which is the research and development services culminating in the delivery of two custom assays.

The quarterly project management fees and the initial set-up fee will be recognized as the custom assay development services are performed on a proportional performance basis. Each custom assay development fee will also be recognized on a proportional performance basis as these services are provided, which is consistent with the Company's policy for deliverables or units of

accounting that include milestones. Because they are contingent upon completion of each individual phase of the design project and the decision by BMS to proceed to the next phase and therefore are considered to be substantive milestones, the amount recognized will be limited to that which BMS is contractually obligated to pay upon completion of that phase.

For the three and nine months ended September 30, 2016, $128,630 and $158,192, respectively, was recognized as service revenue under the agreement and $160,106 was recognized as deferred revenue as of September 30, 2016.

Note 10. Net Loss Per Share

Net loss per share attributable to common stockholders is computed by dividing the net loss allocable to common stockholders by the weighted-average number of shares of common stock or common stock equivalents outstanding. Outstanding stock options, warrants and convertible preferred stock have not been included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive. Accordingly, the numerator and the denominator used in computing both basic and diluted net loss per share for each period are the same. The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss per share for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	$ (6,488,442)	$ (5,157,663)	$ (20,366,469)	$ (15,698,139)
Accretion of stock issuance costs	—	—	—	(35,046)
Accretion of discount on Series E warrants	—	—	—	(127,616)
Series E and D, Convertible Preferred Stock dividends	—	—	—	(1,165,932)
Net loss attributable to common stockholders	$ (6,488,442)	$ (5,157,663)	$ (20,366,469)	$ (17,026,733)
Denominator:				
Weighted-average common shares outstanding-basic and diluted	7,053,010	6,829,687	6,985,924	3,735,852
Net loss per share attributable to common stockholders, basic and diluted	$ (0.92)	$ (0.76)	$ (2.92)	$ (4.56)

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

	Nine Months Ended September 30,	
	2016	2015
Options to purchase common stock	1,200,644	590,139
Common stock warrant	219,723	170,587
Restricted stock units	350,499	27,500

Note 11. 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.

On August 22, 2014, in connection with the Company's entry into the Growth Term Loan, the Company issued to the lenders warrants exercisable for an aggregate of 2,512,562 shares of Series E stock at a price of $0.2189 per share. The warrants provide for cashless exercise at the option of the holders, and also contain provisions for the adjustment of the number of shares issuable upon the exercise of the warrant in the event of stock splits, recapitalizations, reclassifications, consolidations or dilutive issuances. In connection with the closing of the Company's IPO in May 2015, the warrants became exercisable for an aggregate of 23,396 shares of common stock at an exercise price of $23.51 per share. The warrants expire by their terms on August 22, 2024, provided that the warrants will be automatically exercised on a cashless basis upon expiration if not previously exercised if the fair market value of a share of the common stock exceeds the per share exercise price. In connection with the funding of the Growth Term Loan B, in March 2016 the Company issued Oxford Finance LLC a common stock warrant exercisable for 45,307 shares of common stock at an exercise price of $2.759 per share, and the warrant issued to Silicon Valley Bank automatically became exercisable for an additional 5,317 shares of common stock at an exercise price of $23.51 per share in accordance with the terms of the Growth Term Loan (see Note 8).

On December 30, 2014, in connection with the Company's Note Agreements (see Note 8) the Company agreed to issue warrants (the "Convertible Note Warrants") exercisable for an aggregate of 9,311,586 shares of Series E Stock at a price of $0.2189 per share, for aggregate consideration of $1,354. The Convertible Note Warrants were issued on January 15, 2015. The warrants provide for cashless exercise at the option of the holders, and also contain provisions for the adjustment of the number of shares issuable upon the exercise of the warrant in the event of stock splits, recapitalizations, reclassifications, consolidations or dilutive issuances. In connection with the closing of the Company's IPO in May 2015, the Convertible Note Warrants became exercisable for an aggregate of 144,772 shares of common stock at the IPO price of $14.00 per share. The Convertible Note Warrants expire by their terms on January 15, 2022. As the Convertible Note Warrants were issued in conjunction with and in order to establish a lending facility commitment, they were being accounted for as a debt discount to be amortized over the life of the Note Agreements using the effective interest method and as a warrant liability, at fair value, as they were indexed to shares that could be redeemed for cash outside the control of the Company.

The Company's previously outstanding Series C-1 preferred stock warrants expired upon closing of the IPO as they were not exercised prior to or contemporaneously with the closing of the IPO. As of May 11, 2015, 1,290,350 Series C-1 preferred stock warrants were forfeited and cancelled as they were not exercised prior to the IPO.

In connection with the closing of the Company's IPO in May 2015, then outstanding Series C-2 preferred stock warrants became exercisable for an aggregate of 1,488 shares of common stock at an exercise price of $24.23 per share. These warrants expired by their terms and without exercise in December 2015.

In connection with the closing of the Company's IPO in May 2015, the Company issued an aggregate of 6,729 shares of common stock to the holders of Series D preferred stock warrants, and received aggregate cash consideration for such exercise of $1,752.

The following table shows the warrants outstanding by series as of September 30, 2016 and December 31, 2015.

Series of Warrants	Shares of Common Stock Underlying Warrants at September 30, 2016	Shares of Common Stock Underlying Warrants at December 31, 2015	Exercise Price/Share	Expiration Date
Series E redeemable convertible preferred stock warrants	28,713	23,396	23.51	2024
Convertible note warrants	144,772	144,772	14.00	2022
Common stock warrants	931	931	6.45	2019
Common stock warrants	45,307	—	2.76	2026

During the nine months ended September 30, 2015 the Company recorded a loss of $239,683 on the change in fair value of the preferred stock and convertible note warrants. The fair value of all preferred stock and convertible note warrants was updated prior to conversion at IPO, with the fair value change being charged to loss from change in stock warrant valuation in the condensed statements of operations. There was no similar loss recorded for the three months ended September 30, 2015 and the three and nine months ended September 30, 2016. The preferred stock warrant liability for outstanding Series C-2, Series D and Series E warrants was reclassified to additional paid-in-capital and recorded as common stock warrants upon the closing of the Company's IPO. As such, the fair value of the preferred stock warrant liability was $0 at both September 30, 2016 and December 31, 2015.

Note 12. Redeemable Convertible Preferred Stock

On February 4, 2014, the Company entered into the Series E Preferred Stock and Warrant Purchase Agreement (the "Series E Agreement") authorizing the sale and issuance of up to 99,132,024 shares of its Series E Stock for $0.2189 per share and warrants (the "Series E Warrants") to purchase up to an aggregate of 33,044,008 shares of Series E Stock at an exercise price of $0.001 per share. Pursuant to the Series E Agreement, up to 49,566,012 shares of Series E Stock together with Series E Warrants to purchase up to an aggregate of 16,522,004 shares of Series E Stock would be offered at one or more closings of a first tranche and the remainder of which would be offered in a second tranche.

In connection with the Series E Preferred Agreement, the Company's authorized shares were increased to 600,000,000 shares of Common Stock and 472,083,383 shares of Preferred Stock.

On February 4, 2014 the Company issued 34,099,476 shares of Series E Stock pursuant to the Series E Agreement at a price per share of $0.2189 per share. Along with the shares of Series E Stock, one Series E Warrant was issued for every three shares of Series E Stock purchased with a purchase price of $0.0001 per Series E Warrant and an exercise price of $0.001 per share of Series E Stock for

a total of 11,366,486 Series E Warrants. Each Series E Stock purchaser was required to exercise the Series E Warrant in a simultaneous transaction with the purchase of shares of Series E Stock. The Company received aggregate gross proceeds of $7,476,879 from these issuances.

On March 31, 2014, pursuant to a rights offering, the Company issued 354,062 shares of Series E Stock pursuant to the Series E Agreement at a price per share of $0.2189 per share. Along with the shares of Series E Stock, one Series E Warrant was issued for each three shares of Series E Stock purchased with a purchase price of $0.0001 per Series E Warrant and an exercise price of $0.001 per share of Series E Stock for a total of 118,017 Series E Warrants. Each Series E Stock purchaser was required to exercise the Series E Warrant in a simultaneous transaction with the purchase of shares of Series E Stock. The Company received aggregate proceeds of $77,634 for these issuances. The Series E Agreement provided for a second tranche on or before November 30, 2014, contingent upon the achievement of certain milestones.

It was determined that, given the nominal strike price of the Series E Warrants and the fact that the Series E Preferred Warrants were required to be exercised immediately upon issuance, the per share value of the Series E Warrants would be similar to the effective per share value of the Series E Stock, or $0.1645 per share.

The second closing under the Series E Agreement, originally scheduled to occur on or before November 31, 2014, was replaced by an alternative financing in the form of subordinated convertible notes as discussed further in Note 8.

The Series A/B/C/D Stock and Series E Stock had a par value of $0.001 per share.

The Series D Stock and Series E Stock liquidation preference was equal to two times the original issue price of the Series D Stock or Series E Stock, respectively, plus any accrued but unpaid dividends whether or not declared. The Company has historically accreted up to the redemption amount and not the liquidation value, because additional amounts due under the liquidation rights was not considered probable at initial recording or as of the Company's initial public offering in May 2015 or at December 31, 2014.

The shares of Series A/B/C/D Stock and Series E Stock historically had the right to redemption of their respective class of shares on a date beginning not prior to February 2019 (the "Series E Preferred Stock Redemption Date"). In order to affect each respective redemption, the holders of at least 60% of the voting power of the then outstanding shares of Series D Stock or Series E Stock needed to vote in favor of a Series D or Series E Stock redemption and provide written notice to the Company at lease sixty days prior to the Series E Preferred Stock Redemption Date of such election. The holders of at least a majority in the voting power of the then outstanding shares of the Series A/B/C Stock could then vote in favor of a Series A/B/C Stock redemption, respectively. The holders of at least 66 2/3% of the voting power of the then outstanding shares of Series A Redeemable Convertible Preferred Stock ("Series A Stock") could then vote in favor of a Series A Stock redemption. The Series D Stock and Series E Stock redemption value was equal to the Series D Stock and Series E Stock original issue price per share (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like) plus all dividends declared but unpaid thereon together with any accruing dividends accrued but unpaid thereon, whether or not declared with respect to such shares. The Series A/B/C/D and Series E Stock redemption value was equal to the respective series original issue price per share (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like) plus all accrued and unpaid dividends with respect to such shares. If the Company did not have sufficient funds or other assets legally available to redeem all shares to be redeemed at any redemption date, it was to redeem as applicable (i) pro rata to Series E Stock, until all shares were redeemed, (ii) pro rata to Series D Stock until all shares were redeemed, (iii) pro rata to Series C Stock, until all shares were redeemed, (iv) pro rata to Series A Stock and Series B Stock, until all shares were redeemed. If any shares to be redeemed remained outstanding, the Company was to redeem the remaining shares in accordance with the previous sentence as soon as sufficient funds were legally available. Due to the redemption feature, the preferred shares were historically recorded as mezzanine equity.

Preferred Shares	Carrying Value at 5/11/15	Preferred Shares Before IPO	Common Shares After IPO
Series A Stock	$ 1,403,007	1,292,084	38,973
Series B Stock	2,100,149	6,789,712	75,835
Series C-1 Stock	4,569,063	13,242,612	191,406
Series C-2 Stock	2,225,619	9,948,331	93,757
Series D Stock	30,370,273	140,252,678	1,305,984
Series E Stock	7,879,873	45,989,722	428,237
Carrying value, excluding dividends	$ 48,547,984	217,515,139	2,134,192
Series D Stock and Series E Stock cumulative dividends	8,808,065	—	374,632
Total	$ 57,356,049	217,515,139	2,508,824

As of the Company's IPO in May 2015, Series A Stock, Series B Stock, Series C-1 Stock, Series C-2 Stock, Series D Stock and Series E Stock conversion ratios were 0.030, 0.011, 0.014, 0.009, 0.009 and 0.009, respectively, after consideration of the one-for-107.39 reverse split. When converted at May 11, 2015, all of the outstanding preferred shares and cumulative accrued dividends on Series D Stock and Series E Stock were converted into 2,134,192 and 374,632 shares of common stock, respectively.

The Company has historically accounted for the Series E Warrants as liabilities as such warrants were indexed to shares that could be redeemed for cash outside the control of the Company. The Company allocated the total proceeds first to the Series E Warrants based on their fair value of approximately $1,890,000 and the remainder amounting to approximately $5,665,000 of the proceeds allocated to the Preferred Shares. The fair value of the Series E Warrants was estimated to approximate the fair value of the Series E Stock because of their nominal price. The amount allocated to the Series E Warrants represented a discount to the Preferred Shares and was being accreted using the effective interest method up to the redemption amount from the respective issuance date to redemption date of five years. Accretion for the three and nine months ended September 30, 2016 was $0, and accretion for the three and nine months ended September 30, 2015 was approximately $0 and $128,000, respectively. Upon immediate exercise of the Series E Warrants, the amount recorded as warrant liability was reclassified to Preferred Shares, and issuance costs of $48,384, which had been allocated to the warrants were expensed. The Company was not accreting to the amount resulting from additional liquidation preference rights under the agreement because they were not considered probable at initial recording or at any point between then and May 2015 IPO. The Company additionally analyzed the issuance of Series E Warrants with the Series E Stock, noting there was no resulting beneficial conversion feature. Following the IPO, all outstanding warrants previously exercisable for preferred stock became exercisable for common stock. The previously reported warrant liability associated with the convertible warrants was applied to additional paid-in-capital.

The Company's Series D Stock and Series E Stock accrued cumulative dividends at 8% per annum on the original issue price of $0.2189, whether or not declared by the board of directors. In connection with the Company's Growth Term Loan, the holders of both the Series D Stock and Series E Stock agreed to waive their rights to cash dividends. As a result, only a share dividend, based on the cumulative dividends divided by the original issue price, could be paid upon declaration by the board of directors or upon the automatic conversion of the Company's Preferred Stock. Dividends were being accreted based on the number of days outstanding. All shares of Series D and Series E, together with accrued dividends, automatically converted into 374,632 shares of the Company's common stock (on as converted method) in connection with the initial closing of the IPO on May 11, 2015.

Note 13. Stockholders' Equity

Common Stock

The Company amended its certificate of incorporation on May 11, 2015, to decrease the number of authorized shares of common stock from 600,000,000 to 200,000,000 shares. The 200,000,000 authorized shares of common stock have a par value of $0.001 per share. As of September 30, 2016, 7,060,269 and 7,058,873 shares were issued and outstanding, respectively. As of December 31, 2015, 6,845,638 and 6,844,242 shares were issued and outstanding, respectively.

Preferred Stock

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue 10,000,000 shares of preferred stock, each having a par value of $0.001. The preferred stock may be issued from time to time in one or more series with the authorization of the Company's board of directors, with such voting, conversion and other rights and preferences as the board of directors may determine. No shares of preferred stock have been issued to date.

Stock-based Compensation

2014 Equity Incentive Plan

As of September 30, 2016, there were 68,450 shares available for issuance under the Company's 2014 equity incentive plan and options to purchase 1,200,644 shares of common stock were outstanding, including 571,800 options that were fully vested. As of September 30, 2016, there was total unrecognized compensation expense of $1,064,203 related to unvested stock options, which the Company expects to recognize over a weighted-average period of approximately 2.41 years.

In April 2016, in connection with the severance of an employee, the Company accelerated the vesting of 8,957 unvested stock options, as well as the period following termination whereby all of the employee's vested stock options, including those accelerated as part of the severance agreement, could be exercised for a two year period from the termination date. As a result of this modification, the Company recorded incremental stock-based compensation expense of approximately $0 and $13,500 for the three and nine months ended September 30, 2016.

A summary of the Plans' stock option activity 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, 2015	736,645	$ 4.18	7.5	$ 947,794
Granted	548,400	2.47		
Exercised	(4,712)	2.15		
Forfeited	(79,689)	4.90		
Balance at September 30, 2016	1,200,644	$ 3.36	7.9	$ 48,246
Vested and expected to vest at September 30, 2016	1,111,699	$ 3.37	7.8	$ 48,086
Exercisable at September 30, 2016	571,800	$ 3.44	6.5	$ 40,266

As of September 30, 2016, there were 350,499 restricted stock units ("RSUs") unvested and outstanding. Unrecognized compensation expense related to the remaining RSUs was $730,655 at September 30, 2016, which the Company expects to recognize over a weighted-average remaining service period of one year.

A summary of the Plans' RSU activity is as follows:

	Restricted Stock Units (RSU)	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2015	27,500	$ 5.45
Granted	379,761	2.44
Vested	(36,762)	2.90
Forfeited	(20,000)	2.46
Balance at September 30, 2016	350,499	$ 2.43
Vested and expected to vest at September 30, 2016	333,117	$ 2.43

The stock-based compensation expense recorded in the condensed statements of operations for the three and nine months ended September 30, 2016 was $229,918 and $552,054, respectively, and $77,239 and $223,787 for the three and nine months ended September 30, 2015, respectively.

2014 Employee Stock Purchase Plan

In April 2015, the Company's stockholders approved the 2014 Employee Stock Purchase Plan ("ESPP"), which became effective in May 2015. Initially, the ESPP authorized the issuance of up to 110,820 shares of common stock pursuant to the purchase rights granted to the Company's employees or to employees of the Company's designated affiliates. The number of shares of common stock reserved for issuance automatically increased in accordance with the plan by 68,442 on January 1, 2016. The ESPP enables participants to contribute up to 15% of such participant's eligible compensation during a defined period (not to exceed 27 months) to purchase common stock of the Company. The purchase price of common stock under the ESPP will be the lesser of: (i) 85% of the fair market value of the Company's common stock on the first date of an offering or (2) 85% of the fair market value of a share of the Company's common stock on the date of purchase. As of September 30, 2016, 39,978 shares of stock have been purchased under the ESPP since its initiation in January 2016 at a weighted average price per share of $2.54.

Note 14. Commitments and Contingencies

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.

Severance Agreements

The Company has entered into employment agreements or other arrangements with certain executive officers which provide salary continuation payments, bonuses and, in certain instances, the acceleration of the vesting of certain equity awards to individuals in the event that the individual is terminated other than for cause, as defined in the applicable agreements or arrangements.

Indemnification Agreements

In the course of operating its business, the Company has entered into, and continues to enter into, separate indemnification agreements with the Company's directors and executive officers, in addition to the indemnification provided for in the Company's amended and restated bylaws. These agreements may require the Company to indemnify its directors and executive officers for certain expenses incurred by a director executive officer in any action or proceeding arising out of their services as one of the Company's directors or executive officers.

Leases

The Company leases office and laboratory space under two non-cancelable operating leases in Tucson, Arizona. The Company amended its facilities leases in August 2015 to extend the terms for approximately five years and to undergo leasehold improvements to expand and improve its existing research, development, operations and administration office facilities. The lease amendment includes an increase of $804,000 in total monthly rent over the remaining term of the leases. The landlord constructed certain leasehold improvements as an incentive to extend the leases. The total cost of the improvements constructed by the landlord of $710,000 was capitalized when the construction was completed in February 2016, and is being depreciated over the remaining term of the lease agreement. The incentive of $710,000 has been recognized as deferred rent within other current liabilities and other liabilities on the condensed balance sheets, and is being accreted at $11,833 per month over the lease term as a reduction of rent expense.

As a result of the amendments, the Company's remaining minimum real estate lease payments before common area maintenance charges as of September 30, 2016 are as follows:

2016	$ 126,987
2017	510,125
2018	512,533
2019	514,977
2020	517,457
2021 and beyond	43,139
	$ 2,225,218

As of September 30, 2016, the Company also has capital lease commitments consisting of approximately $148,900 of leases for computer equipment varying in length from 36 to 48 months and an equipment financing arrangement of approximately $36,000 with a vendor that expires in December 2017 that have not been included in the minimum lease payments schedule above.

Merck Non-Exclusive License Agreement

In June 2012, the Company entered into a non-exclusive license agreement with Merck Sharp & Dohme Co. ("Merck") whereby the Company agreed to sublicense certain intellectual property related to breast cancer biomarkers with the intent to develop, manufacture and commercialize a diagnostic test utilizing this technology. The Company agreed to pay Merck certain contingent milestone payments between $50,000 and $1,000,000 and future royalties of 3%-6% of sales derived from such products developed that utilize the licensed technology. No amounts have been accrued or paid under this agreement as the Company has not achieved any of the milestone targets or developed any products that utilize the licensed technology.

Product Warranty

The following is a summary of the Company's general product warranty liability:

	Nine Months Ended September 30, 2016	2015
Beginning balance	$ 20,213	$ —
Cost of warranty claims	(67,663)	(545)
Warranty accrual	83,745	17,225
Ending balance	$ 36,295	$ 16,680

Warranty accrual is included in accrued liabilities in the condensed balance sheets as of September 30, 2016 and December 31, 2015. Expense relating to the recording of this accrual is recorded in cost of revenue within the 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 the realization of the net deferred tax assets is uncertain. As a result, the Company has not recorded any federal or state income tax benefit in the 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 on audit, including resolution of related appeals or litigation process, if any. 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 September 30, 2016 or December 31, 2015.

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 September 30, 2016 and December 31, 2015, respectively, and has not recognized interest or penalties of significance during the three and nine months ended September 30, 2016 and 2015, respectively, since there are no material unrecognized tax benefits. Management believes no material change to the amount of unrecognized tax benefits will occur within in the next 12 months.

The Company has established a valuation allowance against the entire tax asset. As a result, the Company does not recognize any tax benefit until it is in a taxpaying position and, therefore, more likely to realize the tax benefit. Past and subsequent equity offerings by the Company, and other transactions that have an impact on the Company's ownership structure, may trigger Sections 382 and 383 provisions of the Internal Revenue Code of 1986, as amended, on special limitations on net operating losses and credits following 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.

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, 2015 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 24, 2016. 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 HTG Edge or HTG EdgeSeq systems and related applications and assays;
- our ability to generate sufficient revenue or raise additional capital to meet our working capital needs;
- our ability to secure regulatory clearance or approval, domestically and internationally, for the clinical use of our products;
- our ability to develop new technologies beyond wild-type mRNA and miRNA expression to include DNA, RNA or DNA fusions (or other gene rearrangements), RNA or DNA mutations, DNA copy number variations or other technologies to expand our product offerings;
- 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, or NGS, instruments and consumables, manufacturers and distributors of our products, and third parties who conduct our clinical studies;
- our intellectual property position;
- our expected use of proceeds from our initial public offering;
- 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;
- any estimates regarding expenses, future 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," "expects," "intend," "may," "plan," "potential," "predict," "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 based on a novel technology platform to facilitate the routine use of complex molecular profiling. 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 next generation sequencing (NGS), the movement to less invasive biopsies, the need for greater diagnostic sensitivity, the need to fit into healthcare economics and the need to have automation and workflow for easy deployment. Our HTG Edge and HTG EdgeSeq platforms automate sample processing and can quickly, robustly and simultaneously profile hundreds or thousands of molecular targets from samples a fraction of the size required by prevailing technologies. Our objective is to establish our platforms as standards in molecular profiling and make this capability 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 collect such information locally to minimize turnaround time and cost.

Our HTG Edge system is capable of running both our original, plate-based chemistry, which quantifies RNA using our plate reader included with the system, and our HTG EdgeSeq chemistry, which is detected using NGS instrumentation provided by the end user. We also plan to launch a new version of our HTG EdgeSeq system that will target the low-throughput lab market. This program, referred to as "Project JANUS", is expected to increase our addressable market by enabling efficient molecular profiling of smaller quantity batches of samples. Though we have temporarily suspended Project JANUS in favor of other high value projects that we expect to provide greater short term benefits, we remain committed to Project JANUS and the development of an HTG EdgeSeq system that will target the low-throughput lab market.

Our innovative platforms and menu of molecular profiling panels are 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 substantially improve the lab's workflow efficiency. Customers are also now able to access our technology via the VERI/O service laboratory. We currently market several proprietary molecular profiling panels that address the needs of customers in translational research, biomarker discovery 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 incurred significant losses since our inception, and we have never been profitable. We incurred net losses of $6.5 million and $20.4 million for the three and nine months ended September 30, 2016, respectively, and net losses of $5.2 million and $15.7 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $109.9 million and we had available cash and cash equivalents totaling approximately $5.5 million and investments in highly liquid corporate and government debt securities totaling $11.1 million.

Recent Developments

In October 2016, we entered into a broad, non-exclusive companion diagnostics master agreement with Merck KGaA, Darmstadt, Germany to facilitate collaboration between the parties in the potential development of companion diagnostics by creating a legal framework which sets forth terms and conditions of the parties' collaboration in connection with future development programs. The initial development program under the agreement utilizes our HTG EdgeSeq DLBCL Cell of Origin Assay in the Merck KGaA M7583 program, a selective and irreversible inhibitor of Bruton's Tyrosine Kinase. The agreement is expected to lead to additional collaboration and development opportunities, utilizing our capabilities in assay development, regulatory filings and commercialization of companion diagnostics.

In October 2016, we entered into a distribution agreement for Italy with Gilson Italia srl, further expanding our commercialization capabilities in Europe. We now have direct sales coverage in the United Kingdom, France, Germany, Switzerland, Belgium and the Nordic countries, and distributors in Spain, Portugal, Italy and Israel.

In July 2016, we announced an agreement with Firalis S.A. to develop an NGS-based theranostic tool to predict patient response to anti-TNF-alpha therapies to allow for improved patient management in the treatment of rheumatoid arthritis, or RA. Under the agreement, we have agreed to supply instrumentation and reagents to support Firalis' development, validation and clinical deployment of a biomarker assay to predict treatment response in RA, using the NGS-based HTG EdgeSeq system.

In July 2016, we satisfied the requirements to CE mark our HTG EdgeSeq DLBCL Cell of Origin Assay, which allows us to commercialize this IVD assay in Europe for its diagnostic intended use.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2016 and 2015

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
Revenue:						
Product	$ 506,065	$ 973,956	$ (467,891)	$ 1,683,382	$ 2,349,740	$ (666,358)
Service	407,836	37,000	370,836	1,991,567	150,292	1,841,275
Other	—	—	—	—	325,789	(325,789)
Total revenue	913,901	1,010,956	(97,055)	3,674,949	2,825,821	849,128
Cost of revenue	1,125,009	809,015	315,994	2,901,455	2,538,590	362,865
Gross margin	(211,108)	201,941	(413,049)	773,494	287,231	486,263
Operating expenses:						
Selling, general and administrative	3,937,600	3,717,402	220,198	13,343,945	10,883,161	2,460,784
Research and development	1,910,116	1,309,573	600,543	6,515,808	2,951,009	3,564,799
Total operating expenses	5,847,716	5,026,975	820,741	19,859,753	13,834,170	6,025,583
Operating loss	(6,058,824)	(4,825,034)	(1,233,790)	(19,086,259)	(13,546,939)	(5,539,320)
Other income (expense)						
Loss from change in stock warrant valuation	—	—	—	—	(239,683)	239,683
Interest expense	(490,825)	(378,656)	(112,169)	(1,422,171)	(1,334,103)	(88,068)
Interest income	26,196	37,788	(11,592)	92,767	48,930	43,837
Loss on settlement of convertible debt	—	—	—	—	(705,217)	705,217
Other	35,011	8,239	26,772	53,453	78,873	(25,420)
Total other income (expense)	(429,618)	(332,629)	(96,989)	(1,275,951)	(2,151,200)	875,249
Net loss before income taxes	$(6,488,442)	$(5,157,663)	$(1,330,779)	$(20,362,210)	$(15,698,139)	$(4,664,071)

Revenue

We generate revenue from the sale of our HTG Edge and HTG EdgeSeq platforms, including our HTG Edge and HTG EdgeSeq systems, and our proprietary consumables and related services, such as sample processing and custom assay development for biopharmaceutical companies. Consumables consist primarily of our molecular profiling panels, which we also refer to as assays or tests. Total revenue for the three months ended September 30, 2016 decreased by 10% to $0.9 million compared with $1.0 million for the three months ended September 30, 2015. Total revenue for the nine months ended September 30, 2016 increased by 30% to $3.7 million compared with $2.8 million for the nine months ended September 30, 2015. The overall revenue increase for the nine months ended September 30, 2016 as compared to the same period in the prior year was primarily the result of increased demand for sample processing by our biopharmaceutical company customers, a trend that we expect to continue in future reporting periods. In response to this increased demand for sample processing we announced the formalization of our VERI/O laboratory service in the second quarter of 2016. Revenue for the nine months ended September 30, 2015 included grant revenue that concluded in June of 2015.

Product revenue

Product revenue includes revenue from the sale of instruments and consumables. Total product revenue for the three and nine months ended September 30, 2016 was $0.5 million and $1.7 million, respectively, compared with $1.0 million and $2.3 million for the three and nine months ended September 30, 2015, respectively. Instrument revenue for the three and nine months ended September 30, 2016 was $6,000 and $88,000, respectively, compared with $338,000 and $600,000 for the three and nine months ended September 30, 2015, respectively. Consumables revenue for the three and nine months ended September 30, 2016 was $0.5 million and $1.6 million respectively, compared with $0.6 million and $1.8 million for the three and nine months ended September 30, 2015, respectively. The decrease in product revenue from 2016 to 2015 is primarily attributable to our focus on biopharmaceutical customers whose preference has been to access our technology via services in our VERI/O laboratory. We also experienced a significant reduction in consumable sales to a single customer from 2015 to 2016 upon the customer's completion of a large retrospective sample analysis project in late 2015. While this customer continues to place orders for our miRNA panel, their 2016 consumable orders have been well below their 2015 levels which is not unusual in the research market where revenues are project driven. Despite a reduction in sales to this single customer, our total consumable sales revenue was only slightly below 2015 levels for both the three and nine months ended September 2016, reflecting volume growth from other customers in 2016. We expect to see growth in our product revenue for the remainder of 2016 and into the future, but expect our revenue mix to continue to contain a higher portion of biopharmaceutical service revenue until we enter the clinical diagnostic market.

Service revenue

Service revenue, consisting primarily of sample processing for biopharmaceutical company customers, increased to $0.4 million and $2.0 million for the three and nine months ended September 30, 2016, respectively, compared with $37,000 and $150,000 for the three and nine months ended September 30, 2015, respectively. Service revenue reflects our success with our new and expanding biopharmaceutical collaborations. Our increasing service revenue is the direct result of biopharmaceutical companies who have chosen the HTG EdgeSeq system for use in their drug development programs. These biopharmaceutical service revenues have and are expected to yield standard product gross margins that are consistent with our standard product gross margin targets. For the remainder of 2016, we expect our service revenue to increase in both absolute dollars and as a percentage of total revenue compared with our 2015 service revenue primarily from a projected increase in demand from our biopharmaceutical company customers.

Other revenue

Other revenue was $0 for both the three and nine months ended September 30, 2016 compared with $0 and $326,000 for the three and nine months ended September 30, 2015, respectively. Other revenue consisted of grant funding provided by the U.S. National Institute of Health, or NIH, for a Phase 2 grant completed in June 2015.

Cost of revenue

Cost of revenue increased by $316,000, or 39%, and $363,000, or 14% in the three and nine months ended September 30, 2016, respectively, compared with the three and nine months ended September 30, 2015. Overall cost of revenue increased from 2015 to 2016, driven primarily by a $291,700 provision for excess inventory recorded within cost of revenue in the condensed statements of operations in the third quarter of 2016. We reserved the remaining value of our Edge reader inventory which is no longer in sufficient demand as we have transitioned our panels onto our HTG EdgeSeq platform. Since 2014, we have directed most of our commercial and marketing efforts to our HTG EdgeSeq products that do not utilize the original, chemiluminescent reader technology. As a direct result of this non-cash reserve charge, our gross margin was -23% and 21% for the three and nine months ended September 30, 2016, respectively, when compared with 20% and 10% for the three and nine months ended September 30, 2015. Despite the excess inventory charge, our gross margin for the nine months ended September 30, 2016 was over 10% higher than the same period in 2015. Excluding the impact of this inventory reserve adjustment, gross margin for the three and nine months ended September 30, 2016 was 9% and 29%. Our gross margin for the nine months ended September 30, 2016 reflects expectation of further improvement in our overall gross margin as our product and service revenues increase, allowing us to further absorb our largely fixed manufacturing costs. These costs include increased rental costs incurred in our recent improvement and expansion of our dedicated manufacturing and operations space.

Selling, general and administrative expenses

Selling, general and administrative expenses were $3.9 million and $13.3 million for the three and nine months ended September 30, 2016, respectively, compared with $3.7 million and $10.9 million for the three and nine months ended September 30, 2015, respectively. The increase in both periods was driven primarily by higher sales and marketing costs related to a reorganization of our commercial sales team, expansion of marketing efforts to accelerate market adoption of our products and commissions on increased revenue generated in 2016. Our general and administrative costs decreased by $0.1 million for the three months ended September 30, 2016 when compared to the same period in 2015, and increased by $0.6 million for the nine months ended September 30, 2016 when compared with the nine months ended September 30, 2015. The increase during the nine months ended September 30, 2016 is due primarily to legal and professional fees, non-cash stock-based compensation expense and director and officer insurance premiums, all related to being a public company. Selling, general and administrative expenses for the third quarter of 2016 were consistent with the third quarter of 2015 and with the first half of 2016 as we continue to focus on commercialization of our products and services both domestically and in Europe.

Research and development expenses

Research and development expenses were $1.9 million and $6.5 million for the three and nine months ended September 30, 2016, respectively, compared with $1.3 million and $3.0 million for the three and nine months ended September 30, 2015, respectively. These increases were driven by research and development headcount growth and other direct costs to obtain FDA approval for our first IVD panel and the HTG EdgeSeq system, Project JANUS and menu expansion programs. Specifically, Project JANUS development costs of $0.3 million and $2.3 million for the three and nine months ended September 30, 2016, respectively, comprise the largest portion of this period over period increase. Research and development expenses have decreased and are expected to continue to decrease from expenditures in the first half of the year, due to the temporary suspension of Project JANUS early in the third quarter 2016 in favor of a focus on obtaining our initial FDA approval and other high value and lower cost near term development projects.

Loss from change in stock warrant valuation

Loss from the change in stock warrant valuation for the nine months ended September 30, 2015 was a result of an increase in the fair value of our preferred stock warrants just prior to the exercise of Series D preferred stock warrants, the conversion to common stock warrants of our Series C-2 preferred stock warrants, convertible note warrants and growth term loan warrants at the time of our IPO as a result of the proximity to and assessed likelihood of a successful IPO. There was no loss from change in stock warrant valuation for the third quarter of 2015 or for the three and nine months ended September 30, 2016 as the warrants were converted to common stock warrants with completion of the IPO in May 2015.

Interest expense and loss on settlement of convertible debt

Interest expense was $0.5 million and $1.4 million for the three and nine months ended September 30, 2016, respectively, as compared with $0.4 million and $1.3 million for the three and nine months ended September 30, 2015, respectively. The increase related primarily to accrued interest incurred on the $5.0 million growth term loan borrowed in March 2016.

For the nine months ended September 30, 2015, our remaining convertible note debt discount and deferred financing costs relating to the convertible note totaling $0.7 million were charged to loss on settlement of convertible debt with the issuance of common stock in settlement of the convertible notes and related accrued interest with the completion of the IPO. There were no convertible notes outstanding during the three months ended September 30, 2015 or for either the three or nine months ended September 30, 2016.

Cash Flows for the Nine Months Ended September 30, 2016 and 2015

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

	Nine Months Ended September 30,	
	2016	2015
Net cash provided by (used in):		
Operating activities	$ (17,312,741)	$ (14,686,243)
Investing activities	17,759,574	(37,424,235)
Financing activities	1,783,008	51,095,229
Increase (decrease) in cash and cash equivalents	$ 2,229,841	$ (1,015,249)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2016 was $17.3 million and reflected (i) the net loss of $20.4 million, (ii) net non-cash items of $2.7 million, consisting primarily of depreciation and amortization of $1.1 million, amortization of the discount on the NuvoGen obligation and of the discount, final payment premium and deferred financing costs on the growth term loan of $0.6 million, stock-based compensation of $0.6 million, a provision for excess inventory of $0.4 million, and accrued interest on available-for-sale securities of $0.1 million, and (iii) a net cash inflow from changes in balances of operating assets and liabilities of $0.4 million, consisting primarily of decrease in accounts receivable due to collections efforts in the third quarter 2016 and increased deferred revenue due to longer term biopharmaceutical company customer service contracts, partially offset by increased accounts payable primarily relating to research and development project expenses.

Net cash used in operating activities for the nine months ended September 30, 2015 was $14.7 million and reflected (i) the net loss of $15.7 million, (ii) net non-cash items of $2.6 million, consisting primarily of amortization and write off at IPO of discount on convertible notes of $0.7 million, depreciation and amortization of $0.5 million, amortization of the discount on the NuvoGen obligation of $0.2 million, provision for excess inventory of $0.3 million, stock-based compensation of $0.2 million and a decrease in the warrant valuation of $0.2 million and (iii) a net cash outflow from changes in balances of operating assets and liabilities of $1.6 million. The significant items comprising the changes in balances of operating assets and liabilities were an increase of $0.9 million in inventory and an increase in prepaid and other of $0.5 million partially offset by a decrease in accounts payable and accrued liabilities.

Investing Activities

Net cash provided by investing activities of $17.8 million for the nine months ended September 30, 2016 was comprised primarily of available-for-sale securities activities, including maturities of $23.0 million and purchases of $3.4 million of available-for-sale securities during the period. Our investing activities for the nine months ended September 30, 2015 were comprised

primarily of the purchase of $43.0 million and disposals of $6.5 million of available-for-sale securities with proceeds from our IPO in May 2015.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2016 consisted primarily of $5.0 million in proceeds from the draw of our growth term loan B availability in March 2016 to fund ongoing business operations, partially offset by $2.9 million in payments on the outstanding growth term loan balance that began in April 2016.

Net cash provided by financing activities for the nine months ended September 30, 2015 of $51.1 million included $47.7 million proceeds from our initial public offering, partially offset by $1.0 million deferred offering costs incurred in the period, and $4.5 million in proceeds from convertible notes.

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. Through September 30, 2016, we had received net proceeds of $52.9 million from the issuances of preferred stock, including preferred stock issued on conversion of promissory notes, $45.4 million of net proceeds from the issuance of our common stock, $0.8 million in proceeds from a prior term loan, approximately $7.7 million in grants, $15.6 million from our growth term loan (net of $0.4 million original issue discount), $4.5 million from convertible note issuances and $35.0 million from service and product revenue. As of September 30, 2016, we had $16.6 million in cash, cash equivalents and short-term available-for-sale investments and $22.1 million of debt outstanding on our growth term loan payable, NuvoGen obligation and capital lease obligations. Amounts due on the convertible notes as well as the related accrued interest were automatically converted into 324,591 shares of our common stock in connection with the initial closing of our IPO in May 2015.

We have had recurring operating losses and negative cash flows from operations since inception, and we have an accumulated deficit of approximately $109.9 million as of September 30, 2016.

In August 2014, we entered into an asset-secured growth capital term loan with Oxford Finance, LLC and Silicon Valley Bank. We borrowed the first tranche of the term loan in the amount of $11.0 million in August 2014 and the second tranche of the term loan in the amount of $5.0 million in March 2016. The first and second tranches of the term loan accrue interest annually at 8.5% and 8.75%, respectively and mature on September 1, 2018. The term loan was payable in monthly interest-only payments until April 1, 2016, following which date we became obligated to make equal monthly payments consisting of principal and interest amortized over the remaining term of the loan. Payments under the loan could result in a significant reduction of our working capital.

Funding Requirements

We have had recurring operating losses and negative cash flows from operations since our inception and have an accumulated deficit of approximately $109.9 million. As of September 30, 2016, we had cash, cash equivalents and investments in short term available-for-sale securities of approximately $16.6 million, and had current liabilities of approximately $10.0 million plus an additional $6.9 million in long-term liabilities attributable to our growth term loan. We believe that our existing resources will be sufficient to fund our planned operations and expenditures until mid-way through the second quarter of 2017. 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. These circumstances raise substantial doubt about our ability to continue as a going concern.

Until our revenue reaches a level sufficient to support self-sustaining cash flows, if ever, we will 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 product and service revenues, 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 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 or seek other protection from creditors, or liquidate all of our assets.

Contractual Obligations

As of September 30, 2016, there have been no material changes to our contractual obligations and commitments outside of the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations" in our Annual Report on Form 10-K filed with the SEC on March 24, 2016 other than contractual obligations associated with our $5.0 million growth term loan draw in March 2016.

Off-Balance Sheet Arrangements

Through September 30, 2016, 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 – Recent Accounting Pronouncements in the notes to the 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 operation is based on our financial statements, which have been prepared in accordance with 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 position, 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 significant accounting policies and estimates during the nine months ended September 30, 2016 from those set forth in "Critical Accounting Policies and Significant Judgments and Estimates" in our December 31, 2015 Annual Report on Form 10-K filed with the SEC on March 24, 2016.

Emerging Growth Company Status

We are an emerging growth company as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks, including charge in commodity prices and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices. Prices for our products are largely denominated in U.S. dollars and, as a result, we do not face significant risk with respect to foreign currency exchange risks.

Generally, our exposure to market risk has been primarily limited to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly as it relates to our investment in money market funds and debt securities. We had cash and cash equivalents of $5.5 million at September 30, 2016, which consist of money market funds. Such interest-bearing instruments carry a 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. Our debt is at fixed interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements. Our investments in 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, U.S. government sponsored agency obligation and high credit quality corporate debt securities which have an average credit rating of AA. We do not anticipate exposure to significant market risk based upon our conservative investment policy.

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 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 harm our business in the future. 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 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 September 30, 2016, 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.

We are in the very early stages of the costly and challenging process of compiling the systems and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We are not currently required to comply with, and we cannot be certain when we will be able to implement when required the requirements of, Section 404 of the Sarbanes-Oxley Act.

We continue to review, document and test our internal control over financial reporting.

We must perform system and process evaluation and testing of our internal controls over financial reporting, to allow management to report on the effectiveness of our internal controls over financial reporting commencing with our Annual Report on Form 10-K for the year ended December 31, 2016, as required by Section 404 of the Sarbanes-Oxley Act.

We might not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports.

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 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 information about these risks, as well as the other information in this report, 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. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. We have marked with an asterisk (*) those risk factors that did not appear 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 24, 2016.

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 $6.5 million and $20.4 million for the three and nine months ended September 30, 2016, respectively, and net losses of $5.2 million and $15.7 million for the three and nine months ending September 30, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $109.9 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 assay panels, including our initial IVD assay, and the commercialization of our HTG Edge and HTG EdgeSeq systems and our 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, expanding our staff to sell and support our products, and the increased administrative costs associated with being a public company. 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, 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 might not be able to continue as a going concern absent our ability to raise additional equity or debt capital. Even if capital is available, it might be available only on unfavorable terms.*

This Quarterly Report on Form 10-Q for the period ended September 30, 2016, includes disclosures stating that our recurring losses from operations since inception and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern. We have had recurring operating losses and negative cash flows from operations since inception, and we have an accumulated deficit of approximately $109.9 million as of September 30, 2016. As of September 30, 2016, we had cash, cash equivalents and investments in short term available-for-sale securities of approximately $16.6 million, and had current liabilities of approximately $10.0 million plus an additional $6.9 million in long-term liabilities attributable to our growth term loan. We believe that our existing cash resources will be sufficient to fund our planned operations and expenditures until mid-way through the second quarter of 2017. In addition, 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.

To date, 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 Edge and HTG EdgeSeq systems, the sale of our proprietary consumables and related services. We will need to raise additional capital to fund our continued operations until our revenue reaches a level sufficient to provide for self-sustaining cash flows, if ever. There can be no assurance that additional capital will be available to us when needed or on acceptable terms, or that our revenue will reach a level sufficient to provide for self-sustaining cash flows. If we are unable to raise additional capital in the future when required or 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 for our stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets.

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, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

If we obtain additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. If we are unable to continue as a going concern, holders of our common stock or other securities may lose the entire value of their investment.

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

In August 2014, we entered into a $16.0 million term loan agreement with Oxford Finance LLC and Silicon Valley Bank, who we collectively refer to as the lenders. Under the terms of the term loan agreement, the lenders initially provided us with a term loan of $11.0 million. In March 2016, we borrowed the remaining $5.0 million pursuant to the term loan agreement. The loan is secured by a lien covering substantially all of our assets, excluding patents, trademarks and other intellectual property rights (except for rights to payment related to the sale, licensing or disposition of such intellectual property rights) and certain other specified property. The interest-only payment period expired in April 2016, and we are currently required to make monthly principal and interest payments through September 2018. Payments under the term loan agreement could result in a significant reduction of our working capital, which in turn could significantly impact our need to raise additional capital in order to continue as a going concern. As of September 30, 2016, we had $13.2 million outstanding under the term loan agreement, of which amount $6.3 million is scheduled to become due and payable over the 12 months following such date, compared to cash, cash equivalents and investments in short term available-for-sale securities of approximately $16.6 million.

Pursuant to the terms of an asset purchase agreement with NuvoGen Research, LLC, or NuvoGen, pursuant to which we acquired certain intellectual property, we agreed to 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 $5.8 million. We paid our fixed fees for 2015 and the first quarter of 2016 in advance. In April 2016, we resumed quarterly fee payments. For the remainder of 2016 and 2017, we are required to pay a yearly fixed fee, in quarterly installments, to NuvoGen in the range of $543,750 to $800,000, and may defer the accrued revenue-based payments, if any. Beginning in 2018, we are again obligated to pay the greater of $400,000 or 6% of our annual revenue plus amounts, if any, deferred in the 2016 and 2017 periods by which 6% of revenue exceeds the applicable fixed fee plus 5% interest on any such deferred amounts until the obligation is repaid in full. Payments to NuvoGen could result in a significant reduction in our working capital.

Our term loan agreement 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;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- change certain key management personnel; 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 term loan agreement, the lenders could proceed against the collateral granted to them to secure our indebtedness or declare all obligation under the term loan agreement to be due and payable. In certain circumstances, procedures by the lenders could result in a loss by us of all of our equipment and inventory, which are included in the collateral granted to the lenders. If any indebtedness under the term loan agreement were to be accelerated, there can be no assurance that our assets would be sufficient to repay in full that indebtedness. 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.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness under the term loan agreement. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

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 solution or related panels to operate on 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 up to seven 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 an 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 RNA fusions and other gene rearrangements and DNA mutations, such as expressed DNA mutations, and copy number variations, or CNVs. We believe we have successfully demonstrated proof of concept that our technology is able to detect these fusions and expressed DNA mutations, but to date our work in this area has only been on a very small scale or may not have the specificity required for certain applications. We cannot guarantee that we will be able to successfully develop these applications on a commercial scale. If we are unsuccessful at developing additional applications involving RNA fusions, DNA mutations or CNVs, 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 are developing a new version of our HTG EdgeSeq system that will target the lower-volume throughput lab market. This program, which we refer to as Project JANUS, is expected to increase our addressable market by enabling efficient molecular profiling of smaller quantity batches of samples. This program involves the development of new chemistry that is not currently compatible with our existing HTG Edge or HTG EdgeSeq platforms. We have temporarily suspended the development of this program in favor of other high value projects that we expect to provide greater short term benefits, and if we are unable to resume or successfully develop this new version of our HTG EdgeSeq system and on the timeframe we anticipate, 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), single-cell analysis and copy number variation, 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 or discover errors during our product development cycle, the product launch date(s) may be delayed. 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 Edge and HTG EdgeSeq systems 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, academic institutions and molecular labs that perform analyses using our HTG Edge or HTG EdgeSeq systems and consumables for research use only, which means that they may not be used for clinical diagnostic purposes. Our success will depend, in part, upon our ability to increase our market penetration among these customers and to expand our market by developing and marketing new clinical diagnostic tests and research-use-only applications, and to introduce diagnostic products into clinical laboratories 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 and development and manufacturing processes and facilities, 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 any future diagnostic products are effective in obtaining clinically relevant information that can inform treatment decisions, and that our HTG Edge and HTG EdgeSeq systems and related panels can enable an equivalent or superior approach than other available technology. Furthermore, we expect that increasing the installed base of our HTG Edge and HTG EdgeSeq systems will increase demand for our relatively high margin panels. If we are not able to successfully increase our installed base of the HTG Edge and HTG EdgeSeq systems, sales of our panels and our margins may not meet expectations. Attracting new customers and introducing new panels requires substantial time and expense. Any failure to expand our existing customer base, or launch new panels or diagnostic products, 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 in light of 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 and panels, 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, two customers accounted for 45% of our revenue for the year ended December 31, 2015 and the top three customers accounted for 27%, 24% and 9% and 38%, 14% and 7% of our revenue for the three and nine months ended September 30, 2016, respectively. If orders from our top customers 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 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. 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 instruments, 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 instrument sales 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 to purchase systems other than ours.

If the utility of our HTG Edge and HTG EdgeSeq systems, proprietary profiling panels and solutions in development is not supported by studies published in peer-reviewed medical publications, the rate of adoption of our current and future solutions 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 solutions 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 solutions or the technology underlying the HTG Edge and HTG EdgeSeq platforms and future solutions 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 Edge and HTG EdgeSeq systems, our current panels 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 system and related applications provide accurate, reliable, useful and cost-effective information. Peer-reviewed publications regarding our platforms 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 solutions or the technology underlying our HTG Edge and HTG EdgeSeq platforms, our current tests and assays or our future solutions 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 Edge and HTG EdgeSeq systems 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 Edge and HTG EdgeSeq systems and profiling panels under different arrangements in order 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 a decision to purchase is made, 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 reagent rental agreements in 2015 and 2016, 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 conclusion 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 collaboration agreement whereby an academic or a commercial collaborator agrees to provide samples free of charge in exchange for the use of a HTG Edge and/or HTG EdgeSeq system at no cost in furtherance of a research or clinical project.

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 Edge and 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.

A significant amount of our inventory consists of instruments held by prospective customers who are evaluating our products and may not be converted to revenue on the timeframe that we anticipate or at all.*

As of September 30, 2016, approximately $437,000 of our inventory consisted of HTG Edge or HTG EdgeSeq instruments held by customers who are evaluating and testing our products, including our HTG EdgeSeq products. If these prospective customers do not adopt our products within the time periods that we estimate, or at all, then we will not be able to convert the inventory held by these customers into revenues. If we are unable to sell this inventory to other customers or if it becomes obsolete as we introduce and expand the customer base for our dedicated HTG EdgeSeq system, which became available in the third quarter of 2015, we may be required to write off a significant portion of this inventory.

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. 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 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 derived initially from sales of our HTG Edge and HTG EdgeSeq systems, proprietary panels, and the development of custom assays and sample processing for biopharmaceutical companies, academic institutions and molecular labs worldwide for research applications. The demand for our products 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. 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.

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. We currently market our products through our own sales force in the United States and Europe, through a third party contract sales team in Europe and distributors in Spain, Portugal, Israel, Italy and in parts of Asia. In the future, we intend to expand our sales and support team in the United States, continue to build a direct sales and support team in Europe and 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 and potential future diagnostic 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 no experience 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 all or some of our HTG Edge and HTG EdgeSeq systems 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. As a result, before we can market or distribute our profiling panels, including our mRNA and miRNA assays, 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 activated B-cell (ABC) or germinal-center B-cell (GCB) subtype and detect the expression of additional drug-linked gene targets such as PD-1, PD-L1 and CD19. 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 submission process to obtain FDA approval of our HTG EdgeSeq ALK*Plus* Assay to detect certain gene fusions in lung cancer. Pending the outcome of clinical trials, we plan to complete the FDA submission for the HTG EdgeSeq ALK*Plus* Assay by the end of the first quarter of 2017. We cannot provide any assurances that our clinical trial(s) or collaborations with biopharmaceutical companies will 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 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. In July 2016, we obtained the right to CE mark the HTG EdgeSeq DLBCL Cell of Origin assay for sale as an IVD in Europe, and we plan to submit the HTG EdgeSeq ALK*Plus* Assay for European regulatory approval by the end of the fourth quarter of 2016. Once we do apply for the HTG EdgeSeq

Alk*Plus* Assay or any other product, we may not receive ex-U.S. approval for the commercial use of our tests on a timely basis, or at all. If we are unable to achieve appropriate ex-U.S. approvals, or if clinical diagnostic laboratories outside the United States do not accept our tests, our ability to grow our business outside of the United States could be compromised.

Clinical trials 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 studies and clinical trials of our product candidates or experience significant delays in doing so, our business will be materially harmed.*

Our clinical diagnostic business prospects in the U.S. and other applicable jurisdictions will depend on our ability to successfully complete clinical trials for product candidates that we intend to market as IVD kits. A failure of one or more clinical trials can occur at any stage of testing. The outcome of non-clinical studies may not be predictive of the success of clinical trials, and interim results of a clinical trial 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 trials have nonetheless failed to obtain pre-marketing clearance or approval for their products. Completion of clinical trials, announcement of results of the trials and our ability to obtain regulatory approvals could be delayed for a variety of reasons, including:

- unsatisfactory results of any clinical trial, including failure to meet study objectives;
- the failure of our principal third-party investigators to perform our clinical trials on our anticipated schedules;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- our inability to adhere to clinical trial 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 trial;

Our development costs will increase if we have material delays in any clinical trial or if we need to perform more or larger clinical trials 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 trials in a timely manner could jeopardize our ability to obtain regulatory approval.

If our HTG Edge or HTG EdgeSeq systems and proprietary profiling panels fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue, and our prospects may be harmed.

We are currently focused on selling our HTG Edge and HTG EdgeSeq systems and profiling panels within the life sciences research market. We plan to develop panels for many different disease states including companion diagnostics to determine the proper course of medication 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 Edge and HTG EdgeSeq systems and related profiling panels provide equivalent or better diagnostic information than other available technologies and methodologies. We believe our panels represent a new 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, the use of our panels may not become the standard diagnostic tool for those diseases on which we plan to focus our efforts. A portion of our strategy is to develop diagnostic tools in conjunction with biopharmaceutical companies 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, our biopharmaceutical partners may choose alternative diagnostic tests to market with their products instead of ours which could limit our diagnostic test sales and revenues.

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

We have relied, and expect to continue to rely, on strategic collaborations and licensing agreements with third parties to develop or in-license technologies based on which we develop profiling panels. 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 breast-related disorders, lung cancer, melanoma and other diseases. We intend to enter into additional similar agreements with life sciences 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 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 collaborations and licensing arrangements is difficult and time-consuming. Discussions may not lead to 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 we enter into new collaboration 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. Under standard clinical practice, tissue biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format. We rely on our ability to secure access to these archived patient samples, including FFPE tissue, plasma, serum, whole blood preserved in PAX gene, 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. If we are not able to negotiate access to archived patient samples on a timely basis, 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, polymerase chain reaction, or PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well-established laboratory techniques such as microarrays or quantitative PCR, or qPCR, as well as newer technologies such as next generation sequencing. We believe our principal competitors in the life sciences research market are Advanced Cell Diagnostics, Agilent Technologies, Inc., ArcherDx, Inc., BioRad Laboratories, Exiqon A/S, Fluidigm Corporation, Foundation Medicine, Inc. Illumina, Inc., Abbott Molecular, Luminex Corporation, Affymetrix, Inc., NanoString Technologies, Inc., Qiagen N.V., Roche Diagnostics, a division of the Roche Group of companies, and Thermo Fisher Scientific, Inc. In addition, there are a number of other market entrants in the process of developing novel technologies for the life sciences market, including companies such as RainDance Technologies, Inc. and Wafergen Bio-Systems, Inc. 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 Clinical Laboratory Improvement Amendments, or 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 to supply a subcomponent of our systems, and the loss of any of these suppliers could harm our business.*

We currently rely on a single supplier to supply a subcomponent used in our HTG Edge and HTG EdgeSeq processors. Our contracts with this supplier do not commit it to carry inventory or make available any particular quantities, and it 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. We also rely on third-party suppliers for various components we use to manufacture our consumable products. We periodically forecast our needs for such components and enter into standard purchase orders with them. If we were to lose any such suppliers, 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 materials we require for our products, our supply chain would be interrupted which would adversely affect our sales. A loss of any of these suppliers could significantly delay the delivery of HTG Edge or HTG EdgeSeq systems, 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 Edge and HTG EdgeSeq systems.

We recently began manufacturing our HTG Edge and HTG EdgeSeq systems internally. We have limited experience with manufacturing these systems 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 these systems 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 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 Edge and HTG EdgeSeq systems, 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 Edge and HTG EdgeSeq systems in our Tucson, Arizona facilities. In addition, our Tucson facilities are the center for order processing, receipt of critical components of our HTG Edge and HTG EdgeSeq instruments 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 and development 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 floods, 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, process customer samples 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 both the three and nine months ended September 30, 2016, approximately 15% of our revenue was generated from sales to customers located outside of the United States, compared with 24% and 11% for the three and nine months ended September 30, 2015, respectively. We expect that a percentage of our future revenue will continue to come from international sources, 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 and sales partners for sales of our products outside of the United States. *

We have established an exclusive distribution agreement for our HTG Edge and HTG EdgeSeq platforms and related profiling panels within Israel, Spain, Portugal, Italy and parts of Asia. In addition, we have an agreement with a contract sales team in Europe, which we are in the process of transitioning to our own direct sales and support team. 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 types of tissue samples. 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 may, if cleared or approved, in the future use them 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.

The enactment of legislation implementing changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our future financial position and results of operations.

Recent changes to U.S. tax laws, including limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the United States are repatriated to the United States, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any such changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

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

As of December 31, 2015, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $78.5 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 Internal Revenue Code of 1986, as amended, or the Code, 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 an ownership change and may in the future experience one or more additional ownership changes, and as a result, our ability to use 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 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. In particular, the commercialization of our HTG Edge and HTG EdgeSeq systems and related panels requires us to continue to establish and maintain a sales and support team to optimize the market for research tools, then to fully optimize a broad array of diagnostic market opportunities if 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 with 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 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 Edge and 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 is protected through physical and software safeguards, it is still vulnerable to fire, storm, flood, power loss, earthquakes, 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, or RUO, 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", or 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, is in conflict 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 Laboratory Developed Tests, or LDTs, may negatively impact the LDT market and thereby reduce demand for RUO products.

In the event that 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 pre-market approval, 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 trials, 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 in vitro diagnostic 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 approval 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, quality system regulations, or 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 Edge system, 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, or CPT, Editorial Panel recently created new CPT codes that could be used by our customers to report testing for certain large-scale multianalyte genomic sequencing procedures (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 will 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, the Centers for Medicare and Medicaid Services, or 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 Medicare Administrative Contractors, or MACs, such as Palmetto, Novidian, Novitas and Cahaba, were instructed to determine the appropriate fee schedule amounts in the first year, and CMS will calculate 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 25, 2015, CMS released final 2015 pricing for 10 of these codes, and did not issue any pricing on the remaining 19. CPTs 81445 and 81450 for the assessment of 5-50 genes in solid and liquid tumors, respectively, and final gapfill pricing of $597 and $648, respectively, was set for 2015 and is the pricing for 2016. CPT 81455 for the assessment of 51 or more genes in solid and liquid tumors has not yet been priced.

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;
- 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 penalty 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;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or 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 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, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- 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; and
- 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 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 collaboration arrangements 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, 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, or 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, 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, or PAMA, was signed into law, which, among other things, significantly alters the current payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. 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 time 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA or the Affordable Care Act, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, the ACA includes a reduction in the annual update factor used to adjust payments under the CLFS for inflation. This update factor reflects the consumer price index for all urban consumers, or CPI-U, and the ACA reduced the CPI-U by 1.75% for the years 2011 through 2015. The ACA also imposes a multifactor productivity adjustment in addition to the CPI-U, which may further 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 U.S., 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 that applies between January 1, 2016 and December 31, 2017. Absent further legislative action, the tax will be automatically reinstated for medical device sales beginning January 1, 2018. 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. We cannot predict the full impact of the ACA, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred. Further, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, 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 passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless Congressional action is taken. On January 2, 2013, 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. There have been judicial and congressional challenges to certain aspects of the ACA, and we expect additional challenges and amendments in the future.

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 diffuse large B-cell lymphoma 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 which we intend to utilize in developing diagnostic tests for use on our HTG Edge and HTG EdgeSeq systems. 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 Global Market. 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 accounting principles generally accepted in the United States, or GAAP. Commencing with our Annual Report on Form 10-K for the year ending December 31, 2016, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. This 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. We may experience difficulty in meeting these reporting requirements in a timely manner.

We continue to review, document and test our internal control over financial reporting, but we are not currently in compliance with, and we cannot be certain when we will be able to implement the requirements of, Section 404 of the Sarbanes-Oxley Act. We also continue to take steps to remediate identified deficiencies in our internal control over financial reporting. For example, in September 2014, it was determined that we did not have adequate controls in place to properly account for our obligation to NuvoGen in connection with our purchase of intellectual property under an asset purchase agreement, which resulted in a restatement of previously issued financial statements. This deficiency in our internal controls was deemed to be a material weakness. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely 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 SEC or other regulatory authorities.

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, and particularly after we cease to be an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and The NASDAQ Stock Market impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

As an "emerging growth company," we expect to avail 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 May 5, 2015 IPO, 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 $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

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 the NASDAQ Stock Market;
- 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 Quarterly 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 in the event that even a moderate amount of our common stock is sold on the market without commensurate demand.

We may not be able to satisfy the applicable continued listing requirements of The NASDAQ Stock Market.*

Our common stock is currently listed on the NASDAQ Global Market under the symbol "HTGM." On August 15, 2016, we received notice from The NASDAQ Stock Market that our stockholders' equity as reported in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 did not satisfy The NASDAQ Global Market continued listing requirements. Following our submission to NASDAQ of a plan to regain compliance with the stockholders' equity requirements in September 2016, NASDAQ granted us an extension until February 13, 2017 to regain compliance with the stockholders' equity requirement. There can be no assurance that we will be able to regain compliance with the stockholders' equity requirement or satisfy alternative criteria for continued listing on The NASDAQ Global Market, or for listing on any other tier of The NASDAQ Stock Market, such as The NASDAQ Capital Market. If we fail to regain compliance with the applicable criteria for continued listing on The NASDAQ Global Market, or to satisfy the conditions necessary for transferring our listing to The NASDAQ Capital Market, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would likely take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with NASDAQ's listing requirements.

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.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading 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, or the 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 has approved the granting of rights to eligible employees to purchase shares of our common stock pursuant to our 2014 Employee Stock Purchase Plan, or the 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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.*

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned a majority of our capital stock at November 4, 2016. Accordingly, our executive officers, directors and principal stockholders acting together will be able to determine the composition of the board of directors, and may be able to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

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

Use of Proceeds

On May 5, 2015, we commenced our IPO pursuant to a registration statement on Form S-1 (File 333-201313) that was declared effective by the SEC on May 5, 2015 and registered an aggregate of 4,105,500 shares of our common stock for sale to the public at a price of $14.00 per share and an aggregate offering price of approximately $57.5 million. On May 11, 2015 and May 29, 2015, we sold 3,570,000 and 90,076 shares, respectively, to the public at a price of $14.00 per share for an aggregate gross offering price of $51.3 million. Leerink Partners acted as book-running manager for the offering, and Canaccord Genuity and JMP Securities served as co-managers for the offering.

Underwriting discounts and commissions connected with the offering totaled approximately $3.6 million. We incurred additional costs of approximately $2.3 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $5.9 million. Thus net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $45.4 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owing ten percent or more of any class of our equity securities to any other affiliates.

Pending their use, the net proceeds from our IPO are being held in cash and cash equivalents or used to purchase low risk available-for-sale securities, of which $11.1 million were short-term available-for-sale securities, at fair value at September 30, 2016. As of September 30, 2016, we have expended approximately $39.8 million of proceeds from our IPO on the following: (1) approximately $21.0 for sales and marketing and general and administrative expenses; (2) approximately $8.3 million for research and development expansion efforts, including expansion of our research and development team and development of new applications and profiling panels; (3) approximately $4.3 million for the payment of principal and interest on our growth term loan; and (4) approximately $6.2 million to purchase inventory and to fund working capital and other general corporate purposes.

There has been no material change in the expected use of net proceeds from our IPO as described in our final prospectus filed with the SEC on May 6, 2015.

Item 5. Other Information.

None

Item 6. Exhibits.

A list of the exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index, and is incorporated herein by reference.

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: November 14, 2016

By: /s/ Timothy B. Johnson

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

Date: November 14, 2016

By: /s/ Shaun D. McMeans

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

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	Amended and Restated Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated May 11, 2015 (incorporated by reference to Exhibit 4.8 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).
4.9	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 March 31, 2016).
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.

Exhibit Number	Description
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

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 officer(s) 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)) 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) 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

   (c) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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: November 14, 2016

By: /s/ Timothy B. Johnson
Timothy B. Johnson
President and 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 officer(s) 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)) 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) 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

   (c) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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: November 14, 2016

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 September 30, 2016 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: November 14, 2016

By: /s/ Timothy B. Johnson

Timothy B. Johnson
President and 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 September 30, 2016 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: November 14, 2016

By: /s/ Shaun D. McMeans

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