# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2016**

**OR**

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

**Commission File Number 001-37369**

# 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**

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Name of each exchange on which registered** |
|---|---|
| **Common Stock, par value $0.001 per share** | **The NASDAQ Global Market** |

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ (Do not check if a small 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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Global Market on June 30, 2016, was $8,218,698.

The number of shares of Registrant's Common Stock outstanding as of March 17, 2017 was 8,052,451.

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## PART I

Unless the context requires otherwise, references to "HTG," "HTG Molecular Diagnostics," "we," "us" and "our" refer to HTG Molecular Diagnostics, Inc.

### Forward-Looking Statements

This Annual Report on Form 10-K, including the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," may contain forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes, to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- our ability to successfully commercialize our products and services, including our HTG EdgeSeq assays and corresponding automation systems;
- 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 to expand our product offerings, including direct-target sequencing for detection of mutations in genomic DNA and/or expressed RNA (such as single-point mutations and gene rearrangements, like gene fusions and insertions), and methods to detect mutation load and microsatellite instability;
- 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, critical component suppliers, 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;
- our expectations regarding trends in the demand for sample processing by our biopharmaceutical customers;
- 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.

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 filing date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "Risk Factors." 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 may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

**Item 1. Business.**

**Overview**

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

Historically, molecular profiling has faced several technical challenges in clinical applications. These include (i) limited "multiplexing," which means only a few biomarkers could be tested in a single sample, (ii) the need for vast amounts of sample to test more than a few biomarkers, which often required several different technologies conducted in different locations, (iii) complex sample preparation, and (iv) manual and/or time consuming workflows. Even where it was possible to test tens, hundreds or thousands of biomarkers, such as with fixed arrays, data analysis could be quite complicated and time consuming.

Our proprietary technology has several key differentiators, including (i) multiplexing from tens to thousands of biomarkers in a single sample, (ii) very low sample input requirements, (iii) simple, extraction-free sample preparation, which is effective with a wide variety of samples, (iv) automated workflow with sample-to-result turnaround times rivaling any current competitor, and (v) simplified data output. In addition, our HTG EdgeSeq assay technology, launched in 2014, generates a molecular profiling library for detection using NGS. Among other things, NGS provides improved sensitivity and dynamic range for our HTG EdgeSeq assays. We believe these advantages position us to outperform most other now-available molecular profiling technologies, especially in certain sample types, such as formalin-fixed, paraffin-embedded tissue, or FFPE. While we continue to advance our technology, we are particularly focused on gaining market recognition and expanding our product offerings.

Our current sources of revenue include services provided by our VERI/O laboratory (discussed below) and sales of our automation systems and integrated NGS-based HTG EdgeSeq assays. Our current assay product offerings include the following:

- HTG EdgeSeq Oncology Biomarker Panel,
- HTG EdgeSeq Immuno-Oncology Assay,
- HTG EdgeSeq Lymphoma Panel,
- HTG EdgeSeq microRNA Whole-Transcriptome Assay, and
- HTG EdgeSeq DLBCL Cell of Origin Assay.

Our assays are currently sold for research use only, except in Europe where our diffuse large B-cell lymphoma, or DLBCL, assay is CE-marked and available for diagnostic use. In March 2017, we obtained CE-marking of our HTG EdgeSeq ALK*Plus* Assay in Europe, and we continue work on our pre-market approval, or PMA, submission for this assay in the United States. In 2017, we also have a focused development pipeline of new profiling products, which includes planned panels for translational research, drug development, and molecular diagnostics with initial focus in immuno-oncology and next generation pathology. We also expect to complete feasibility testing on several new technological developments, including our direct-target sequencing "version 2" chemistry, or V2 chemistry.

Our HTG EdgeSeq assays are automated on either our HTG Edge or HTG EdgeSeq platform, which may also be referred to as an "instrument" or "processor" and which, together with the assay, is a fully integrated system. Our HTG Edge platform can run both our original, plate-based assays and our NGS-based HTG EdgeSeq assays. We continue to support a small number of customers interested in utilizing our plate-based assays (such as our HTG Edge DMPK Core CYP Assay or otherwise on a custom manufacturing basis); however, in 2016, based on market trends and customer feedback, we shifted our product focus to our NGS-based HTG EdgeSeq system.

Customers can also obtain the advantages of our proprietary technology by engaging our VERI/O laboratory for pre-clinical and clinical research-related services, including drug development and translational research. Our VERI/O lab processes samples for molecular profiling data or, if aligned with our clinical diagnostic product strategy, designs custom research or investigational profiling assays. In 2017, we also expect to deploy our V2 chemistry in the VERI/O lab for detection of DNA mutations.

We believe the value propositions of our products and services are gaining significant recognition. In 2016, we entered into agreements with Bristol-Myers Squibb, or BMS, and Merck KGaA, which are just two examples of the 36 individual project programs with biopharmaceutical companies employing our proprietary technology in their clinical research and drug development programs as of December 31, 2016.

As we navigate product-related regulatory requirements to launch additional molecular diagnostic products, initially in Europe and then in the United States, we expect our research products and services will continue to drive market recognition and technology adoption. Further, we expect that strategically positioning our proprietary technology, products and services in drug or other clinical development programs will drive a future, ongoing portfolio of molecular diagnostic products, including companion diagnostic products.

We have incurred significant losses since our inception, and we have never been profitable. We incurred net losses of $26.0 million and $21.4 million for the years ended December 31, 2016 and 2015, respectively, and we had an accumulated deficit of approximately $115.6 million as of December 31, 2016. As of December 31, 2016, we had available cash and cash equivalents totaling approximately $7.5 million and investments in short-term corporate and government debt securities totaling $4.3 million, and had current liabilities of approximately $10.0 million plus an additional $14.0 million in long-term liabilities primarily attributable to our growth term loan and our obligation to NuvoGen Research LLC, or NuvoGen.

**Our Strategy**

Our objective is to establish the HTG solutions as the standard in molecular profiling, and to make their benefits accessible to all molecular labs from research to the clinic. The key components of our strategy are:

- *Focus on immuno-oncology based molecular profiling*. We plan to develop novel RNA-based gene classifiers to help biopharmaceutical companies and leading translational medicine researchers better understand and predict durable response to immune checkpoint inhibitor drug candidates, such as anti-PD-L1 therapeutics, in mono- and combination therapies. We also plan to develop novel DNA profiling tests that can provide information about mutation load and microsatellite instability, which are genetics factors believed to be associated with response to immune checkpoint inhibitor therapies.
- *Increase and strengthen companion diagnostics collaborations with biopharmaceutical companies.* We believe collaborations with biopharmaceutical companies with late-stage drug development programs will lead to us generating companion diagnostic consumables revenue. As of December 31, 2016, we had 36 active development programs across 16 leading biopharmaceutical companies which are incorporating companion diagnostics in their drug development programs. We plan to expand upon our first companion diagnostic partnership (Merck KGaA for DLBCL cell of origin determination) with additional companion diagnostic collaborations. We have entered into an agreement with QIAGEN Manchester Limited, a subsidiary of QIAGEN, N.V., or QIAGEN, to expand our commercial and technical capabilities in this market. We intend to continue to leverage our VERI/O laboratory services business to enable nimble response to emerging biopharmaceutical molecular profiling requirements.
- *Increase our market adoption by leveraging the advantages of our technology, including low sample input and high sensitivity.* We plan to promote global adoption of our proprietary technology in molecular labs, biopharmaceutical companies and major translational research centers by demonstrating the key differentiating aspects of our chemistry and platforms, such as small sample utilization, multiplexing and high sensitivity. These advantages result in cost, time and ease of use benefits for our customers. To facilitate adoption, we announced and branded our VERI/O service laboratory, in 2016, to support customers who desire additional laboratory capacity, assay design services, and/or to access our service-only content offerings and, in addition, we continue to offer our HTG EdgeSeq system and reagents to customers who want to bring our technology in-house.
- *Establish our systems workflow as the best solution for clinical sequencing*. We intend to continue to establish our technology as the best sample and library preparation method for clinical applications with next generation sequencers. We believe our differentiated HTG EdgeSeq chemistry will accelerate adoption by leveraging the large and growing installed base of next generation sequencers. We are engaged with industry and corporate partners including Illumina, Life Technologies Corporation and QIAGEN, to position our HTG EdgeSeq products as the benchmark for workflow in targeted sequencing applications.

- *Develop new molecular diagnostic panels with high medical utility*. The HTG platforms were developed with features that we believe will enable local molecular labs to routinely test targeted RNA expression, including expressed gene mutations, such as ALK gene rearrangements using our HTG EdgeSeq ALK*Plus* Assay, all from extremely small samples, such as a single five micron section of FFPE tissue. We plan to develop future molecular diagnostic assays in conformance with existing reimbursement codes to facilitate our clinical customers' billings. We also plan to work in the major European medical centers to develop and validate certain solid tumor classifiers and lower cost alternatives for breast and prostate cancer testing.
- *Expand the addressable market of HTG technology through new applications*. We have demonstrated technical feasibility for several new applications that are intended to allow us to measure DNA mutations directly and in expressed RNA, and improve the already-high sensitivity of our HTG EdgeSeq assays. These new applications are expected to allow us to, among other things, develop future "multi-parameter" panels that detect both RNA and DNA targets in a single assay, for use in translational research, companion diagnostics and molecular diagnostics. We believe these applications and panels can be developed efficiently with reasonable capital investment.

**Our Market**

***Development of Molecular Profiling***

Molecular profiling is the analysis of biomarkers, including DNA and RNA and protein, in biological samples, such as tissue, cells, blood and other biofluids, to identify gene expression patterns or genomic changes. New molecular approaches are making it possible to perform these characterizations in unprecedented ways, resulting in a shift from the traditional approach of looking at one target at a time to the simultaneous analysis of potentially tens, hundreds or thousands of targets.

Among what we believe are the most promising applications of molecular profiling is the targeted sequencing of RNA and DNA from patient samples to identify gene expression patterns or molecular markers of disease that can aid in diagnosis, gauge patient prognosis or predict response to an available therapy. These applications have launched a fundamental shift towards personalized medicine where an individual patient's molecular profile is used to guide treatment.

We estimate that the global molecular profiling market is approximately $27.0 billion today. Based on published industry reports, cancer profiling makes up the largest segment of this market at an estimated $17.8 billion, the substantial majority of which we believe currently consists of research-use-only products, and is expected to grow to $35.0 billion by 2018. Our initial diagnostic products target the approximate $4.0 billion pathology related diagnostic markets where we can transition existing testing methods to NGS-based workflows. The companion diagnostic market is currently estimated at $2.5 billion and growing approximately 18% annually. We believe that the acceleration of investment into immuno therapy drugs will also be a catalyst for future companion diagnostics for combination therapies where gene expression classification is expected to be important.

For decades, the treatment of disease was dominated by one-size-fits-all drug regimens. Over the last 10 years, numerous molecular markers and profiling techniques have transitioned from research tools to inclusion in clinical guidelines for patient care. Oncology drug developers have also seen the benefits of molecular markers and today there are many drugs in clinical development with a companion biomarker strategy.

Among the vanguard of these personalized treatments were hormone therapies for breast cancer patients whose tumors expressed the estrogen receptor protein. This was followed using trastuzumab for treating patients with HER2-positive breast cancers. This paradigm shift led to significantly improved patient outcomes when compared to the non-specific, chemotherapeutic approaches used in the past.

The evolution of molecular profiling has also taken shape over the last decade in non-small cell lung cancer, or NSCLC. NSCLC patients were first profiled for EGFR gene mutations to select patients most likely to respond to the drug erlotinib. Next came testing for ALK gene rearrangements as an indicator of response to the drug crizotinib. Now, additional mutations and rearrangements such as ROS1, RET, HER2, KRAS and MET, have been integrated into the NCCN guidelines for the treatment of lung cancer and are used to guide patient treatments.

Similar trends are unfolding in other diseases such as thyroid cancer, colon cancer, and melanoma. These trends are fueling rapid growth of new molecular profiling offerings, technologies and industry business models to support the demand. The fastest growing segment of the estimated $10.6 billion molecular diagnostics market, a subset of the estimated $27.0 billion global molecular profiling market, is clinical testing in oncology. As oncologists rapidly integrate this new level of molecular profiling information into patient management strategies, a growing number of highly specialized central laboratories now offer tests that address specific clinical questions. The trend towards highly multiplexed profiling is not limited to oncology; other examples of expanding demand include prenatal, neonatal, inherited disease, and organ transplant and rejection profiling.

Molecular profiling continues to move into clinical applications, including molecular profiling to develop clinical biomarker strategies, patient stratification for clinical trials, and companion diagnostics. The primary goal is to develop an understanding, at the molecular level, about why a drug does or does not work in a patient population. Variability in patients' gene expression patterns is believed to at least partially explain why the 25% response rate for oncology therapeutics is among the lowest for all disease states.

While the primary objective of these drug-development efforts is to improve response rates, third-party payor pressures to lower patient treatment costs also plays a significant role. As a result, most biopharmaceutical companies develop biomarker strategies to increase the rate of patient response to new drugs in development. Typically, studies will focus on a variety of biological profiling markers that include RNA or protein expression levels, and/or presence or absence of DNA mutations (such as gene fusions and rearrangements), which can be detected in genomic DNA or expressed RNA or protein. Currently, it is estimated that there are over 2,000 clinical trials underway in oncology, and that the clear majority of drug developers believe personalized and targeted therapy development is important to the future success of drug development.

When a molecular biomarker panel is used for selection of patients in a Phase 3 clinical trial to demonstrate safety and efficacy of a new drug, the drug and biomarker test are often submitted to the applicable regulatory agency for approval together. In the United States, upon Food and Drug Administration, or FDA, approval of the biomarker test, or companion diagnostic, the patient must be tested with the companion diagnostic prior to treatment with the drug. Companion diagnostic tests have a clear clinical utility which generally supports favorable reimbursement decisions. We believe there are over 900 active oncology drug development programs, most of which have molecular biomarker strategies, creating a significant opportunity for molecular diagnostic companies with the right molecular profiling solutions.

**Complexities and Challenges of Molecular Profiling Today**

Currently, molecular profiling typically is conducted in the clinical setting using a variety of profiling techniques and instrumentation platforms across multiple laboratory departments, and, in many situations, sent to distant labs. These techniques include immunohistochemistry, or IHC, fluorescent *in situ* hybridization, or FISH, polymerase chain reaction, or PCR, gene expression arrays, or GEA, and NGS. This distributed profiling approach has accelerated the use of molecular profiling and increased the need to make the process more accessible and routine. However, molecular profiling is also highly specialized because current technologies are complex, require multiple capital-intensive workflows, and are not economically scalable to the case volume of the local laboratory. The fragmentation of methods, sample logistics and information flow has created significant challenges for labs, physicians and patients as discussed below.

***Insufficient Sample Availability***

The proliferation of new molecular profiles and technologies has led to the need for more biopsy material to conduct tests of interest. However, the trend is toward less invasive procedures that produce smaller biopsies and thus, in many situations there simply is not enough collected sample to meet all the profiling requirements. For example, historically, the standard method of collecting tumor samples for testing in oncology is via a surgical procedure where the tumor is resected or biopsied and then stabilized, or fixed, in a formaldehyde-based fixative known as formalin. Between 24 to 72 hours after the tissue is removed from the patient, it is permanently stabilized in a hard block of paraffin where it can be stored at room temperature for decades. This preservation technique was developed over 100 years ago, well in advance of the discovery of nucleic acids such as DNA and RNA. While techniques to recover nucleic acids from these FFPE tissue samples have been developed, formalin fixation presents several technical challenges in analyzing DNA and RNA sequences. Because of the convenience of this preservation method, though, FFPE samples are the starting material for almost all tumor-profiling testing in oncology today.

Most commonly, in the past and continuing today, very thin slices of tissue from FFPE blocks, typically five microns in thickness, are affixed to glass slides for testing. Then, a histological stain called an H&E (for the combination of hematoxylin and eosin) is used to differentially mark cellular structures, making it simple for a pathologist to examine the patterns of the normal and diseased tissue under a microscope. IHC stains are also often performed on FFPE tissue slides to aid diagnosis, prognosis or help guide therapy selection, with each IHC stain consuming two slides, one for the stain, and the other for a negative control. Historically, five to ten slides in total were consumed in the complete diagnostic workup for each tumor. With the advent of new molecular techniques there are additional demands for tissue, and most molecular tests on the market today require much more than a single slide. In many clinical situations, there simply is not enough collected tissue to meet all the profiling requirements. The growing number of specialized tumor-profiling tests, and their appetite for FFPE tissue or other sample material, is in direct conflict with the trend towards smaller, less-invasive testing approaches.

***Slow Turnaround Times***

In many cases, turnaround times for comprehensive profiling of a patient's sample(s) are several weeks due to the logistical time to route samples to various laboratory departments and to distant specialized labs. Several technologies for sample characterization

have been used and introduced over the years to determine the status of various molecular characteristics for a sample. These characteristics include RNA and protein expression levels, and/or the presence or absence of DNA mutations, such as single-point mutations and gene fusions and rearrangements, which mutations can be detected in genomic DNA or expressed RNA and protein. A single tumor specimen from a cancer patient is often profiled for multiple molecular characteristics where each characteristic is measured using a different platform. These platforms are utilized in separate laboratory departments or institutions with different technicians and clinicians, requiring that the sample and data be split into multiple workflows. This also requires even more sample consumption.

The time it takes to deliver the final report to a treating physician so that informed treatment decisions may be made is dependent on the turnaround time of the slowest test. A single laboratory with well-choreographed routing of tissues and information may be able to complete sample profiling within a week, but if part of the sample needs to be sent for additional profiling at a specialty lab, the total turnaround time may be lengthened by one or two weeks due to shipping, accessioning by the receiving laboratory and integration of the testing results into the final report.

***Implications of Workflow Inefficiencies on Data Quality and Integration***

In addition to the challenges of splitting a single sample into multiple testing workflows, the individual workflow for molecular profiling of biological samples, including FFPE tissues, is complicated. Many of the steps from sample to result require manual intervention by a molecular technician. While these technicians are trained to standard operating procedures and proficiency tested, the levels of proficiency and precision vary among technicians. Variability introduced by technicians performing manual steps can translate to variability of results, with a test sample frequently at risk of experiencing losses of fidelity through the series of separation and transformation steps.

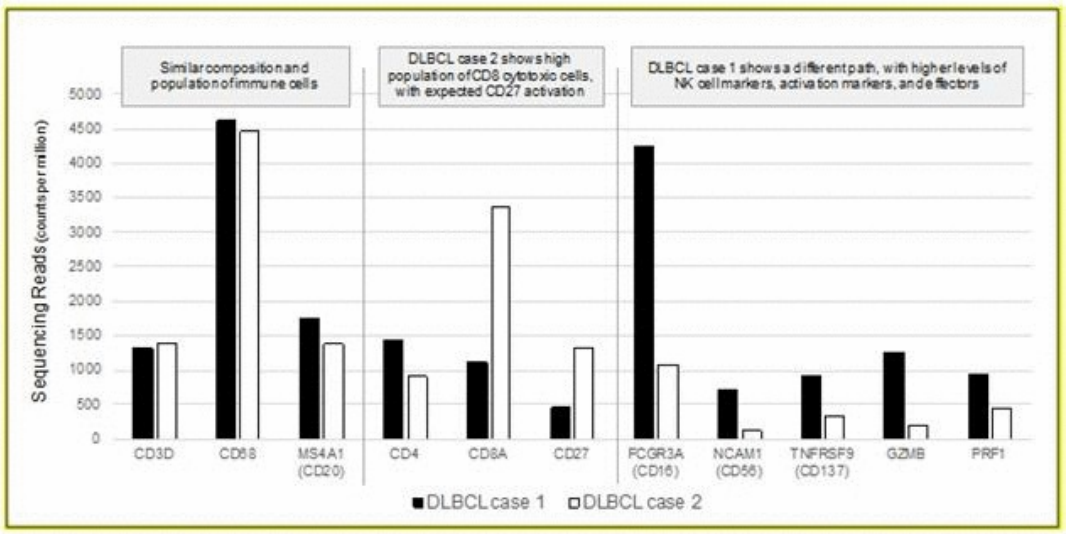
Further, the increase in number of technologies for sample characterization and fragmentation of the testing workflows can also create challenges in putting all the results together in a timely, complete profiling report. This level of data integration is critical for the treating physicians to assure they have the complete molecular assessment prior to consultation with the patient. Without a complete molecular assessment, there is limited ability to discuss the diagnosis, prognosis and treatment options. Overall, we believe the critical relationship between the local pathologist and treating physician has been fractured as many tests results are now sent directly to the treating physician from these specialized and centralized Clinical Laboratory Improvement Amendments, or CLIA, laboratories. We believe the pathologist is critical to aggregating the diagnostic, prognostic and predictive information in a single patient molecular profile that can be utilized by the treating physician for therapeutic decisions.

***Case Study of the Current Limitations in Molecular Profiling: Immuno-Oncology***

A rapidly developing area of oncology drug development is the broad grouping of approaches referred to as immuno-oncology therapies. These immuno-oncology therapeutics include checkpoint inhibitors such as Keytruda (pembrolizumab) for melanoma and NSCLC, cancer vaccines such as chimeric antigen receptors in development by various companies and immunomodulatory therapies such as interferon-alpha. Increasingly, these immuno-therapies are being coupled with more traditional oncology drugs such as tyrosine kinase inhibitors and chemotherapeutics to create synergistic treatment options that attack multiple aspects of the tumor and potentially increase patient response.

While single-biomarker IHC tests have been approved as companion or complimentary diagnostics for anti-PD-1 checkpoint-inhibiting therapies, a proliferation of checkpoint inhibitors targeting additional ligands and receptors for CTLA4, OX40, LAG3, TIM-3 and others, coupled with combination approaches, is challenging the one-biomarker / one-drug diagnostic paradigm that previously advanced IHC-based companion diagnostics (e.g. HER2, ALK, c-KIT, etc). Understanding the complex biological framework of the tumor microenvironment is becoming increasingly important in interpreting the host immune response to tumors and developing the best single or combination therapy approach.

The need for multiplexed gene expression assessment is illustrated in the graphic below where two histologically similar DLBCL tumors elicit very different host immune responses. Both cases have similar tumor composition and large populations of tumor infiltrating lymphocytes (see left-most panel). In case 1, however, the immune system is responding primarily with natural killer lymphocytes, as indicated by the biomarker expression shown in the right-most panel; whereas in case 2, the immune system expresses biomarkers of CD8 cytotoxic lymphocytes (center panel). Based on this information and other clinical parameters, very different immunotherapeutic strategies may be recommended to combat the tumor. We believe that current molecular profiling techniques, like IHC, FISH or RT-qPCR, are ill-suited for comprehensive assessment of the tumor microenvironment at least because of the amount of information (e.g. number of biomarkers) relevant to the clinical decision making that needs to be collected from limited amounts of sample in a time- and cost-efficient way.

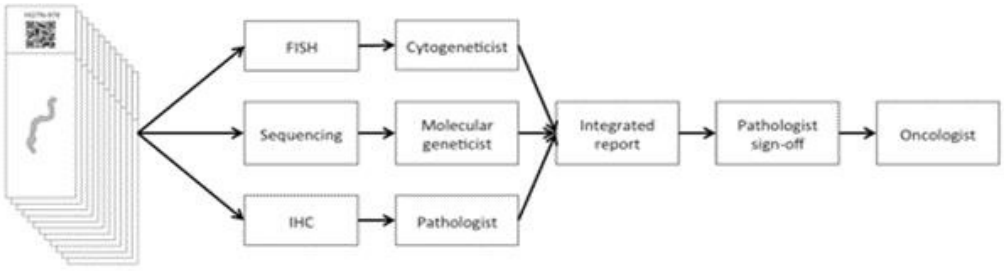



***Case Study of the Current Limitations in Molecular Profiling: NSCLC***

The complexities and potential inefficiencies present in current molecular profiling techniques can be seen in NSCLC. While an increasing number of clinical parameters are being assessed using multiple testing methodologies, the size of the tumor specimen has dramatically decreased, with approximately 70% of lung cancer patients receiving their diagnosis from a small biopsy or cytological specimen. Personalized therapy and entry into clinical trials for NSCLC are heavily dependent on accurate histological classification which is typically performed by IHC. Tumor samples are also routinely tested for various gene mutations and gene rearrangements, with each of these tests performed on a different platform with a disparate workflow.

It is common for each of these platforms to be in separate laboratory departments and/or locations with different technicians and clinicians, requiring that the already small sample be split into multiple workflows. The results from the individual testing workflows are typically aggregated into a single report, signed off by the pathologist and transmitted to the oncologist. As outlined in the diagram below, the multiple steps involved in the process may substantially slow turnaround times and result in an incomplete molecular profile not suitable to inform clinical decision making.

Example of Typical NSCLC Testing Workflow




**Our Solution**

We have developed and sell assays, automation platforms and services based on a proprietary technology that provides precise, efficient molecular profiling of samples for clinical and research purposes. Our proprietary products and services are designed to work with many different biological sample types, can generate robust results from very small samples, and obviate the need for many of the sample-preparation steps associated with traditional molecular profiling techniques. Our platforms and assays enable the simultaneous detection and quantitation of tens, hundreds or thousands of molecular targets and are capable, now or in the future, of profiling multiple parameters such as RNA expression levels, RNA-expressed gene fusions and insertions and DNA mutations in a single testing workflow that can use NGS detection for quantitative measurement.

We manufacture the consumables utilized with our platforms specifically for our platforms and these consumables cannot be obtained from other sources. At the core of our solution is our proprietary chemistry called quantitative nuclease protection, or qNPA. Our qNPA-based chemistries provide an extremely efficient method for analyzing DNA and RNA as it eliminates the need for DNA or RNA extraction or reverse transcription. We designed and developed our HTG automation platforms to optimize the capabilities of our chemistries, provide fast turnaround time and enable ease of use to molecular labs. Our chemistries and automation platforms are highly adaptable, so when molecular profiling needs change or emerge, we expect to be able to efficiently add new applications to address these needs.

The HTG systems provide data in a simple easy to use format. The entire workflow for both systems from sample preparation to a molecular profiling report can be accomplished in 24-36 hours.

We believe most customers in our target markets would prefer to maintain control of their samples and perform the profiling internally but are challenged by limitations in available technologies. We believe we are well positioned to democratize molecular profiling with the following key benefits:

- *Optimize sample utilization*. The HTG systems can analyze as many as 2,500 genes from extremely small sample volumes such as a single five micron section of tissue or 15 microliters of plasma or serum. Our technology allows customers to do more with less, which meets the needs of clinical or pre-clinical laboratories where today there is often not enough patient sample to do all the testing available or desired. We believe providing customers the ability to work with extremely small sample will be a significant driver of adoption of our technology and systems.
- *Compatibility with multiple sample types*. Our HTG systems allow customers to profile and unlock molecular information from a wide variety of biological samples such as FFPE tissue, cells, blood serum and plasma. We have successfully demonstrated the ability to profile these and other sample types, and believe we ultimately can profile most clinically relevant sample types, including cell-free circulating nucleic acids from tumors, a rapidly developing area of investigation which is referred to as a liquid biopsy. We believe that the capabilities of our system will allow us to efficiently expand applications, regardless of sample type.

- *Flexible and adaptable chemistry allows for use in multiple applications*. We believe our proprietary chemistry provides the ability to measure a variety of molecular targets in many necessary applications, including RNA expression levels, expressed RNA gene rearrangements (such as gene fusions and insertions), and DNA point mutations, and offers the ability to quantify these applications on a variety of NGS platforms. This flexibility provides customers the ability to optimize their use of our technologies based on their specific throughput, workflow and application needs. Our proprietary chemistry is comparatively simple, with fewer steps than competing technologies. For example, compared to RT-qPCR, our chemistry does not require extraction or cDNA synthesis. Compared to traditional RNA sequencing, our chemistry does not require extraction, cDNA synthesis, shearing, rRNA depletion, ligation, adenylation, or size selection. We believe that the elimination of these steps helps prevent biases associated with these steps, sample degradation and increased opportunities for technician error.
- *Robust data*. Molecular profiling produces large amounts of information that is used, among other things, to make important decisions, such as identifying potential drug targets or selecting a patient for a therapeutic treatment. This information is valuable only to the extent it accurately represents the true biology of the test sample and the same answer can be produced under many different conditions. Our chemistries are highly specific and sensitive, meaning they can detect the right target even when very little is present in the sample. Our system produces consistent results on a replicate-to-replicate, day-to-day and instrument-to-instrument basis.
- *Automation provides superior workflow and ease of use*. Our technologies are designed with fewer workflow steps in part due to the elimination of the need for complex sample-preparation processes such as extraction, cDNA synthesis, labeling, selection, depletion and shearing. This enables customers to limit hands-on time and the need for specialized skills, resulting in turnaround times of approximately 24-36 hours. Additionally, our HTG EdgeSeq application further integrates sample preparation for targeted sequencing and greatly simplifies the data bioinformatics, so customers looking to leverage their NGS instrument can seamlessly add this capability to their current workflows.
- *Simplified bioinformatics*. Our software provides data in a simple and easy to use format through a simple graphical user interface, or GUI, that is flexible enough for researchers yet structured enough for clinical laboratories. The HTG EdgeSeq parser software, which processes the data from the NGS platform, is modular so that new applications can be downloaded without any changes to hardware. We believe the simplicity of our bioinformatics solution will help drive the adoption of our platform.

***Current Commercial Panels Offered on the HTG Platforms***

We currently market proprietary molecular profiling panels targeting late stage drug development programs with potential breakthrough therapies, such as immuno-oncology. We market these panels to biopharmaceutical companies, with which we collaborate in biomarker development programs. We believe these programs could facilitate our commercialization of companion diagnostic tests. In addition, our panels are used in pre-clinical and clinical research areas, which, we also believe, will facilitate our commercialization of diagnostic tests, including tumor classifiers and prognostic tests. Our currently marketed panels are:

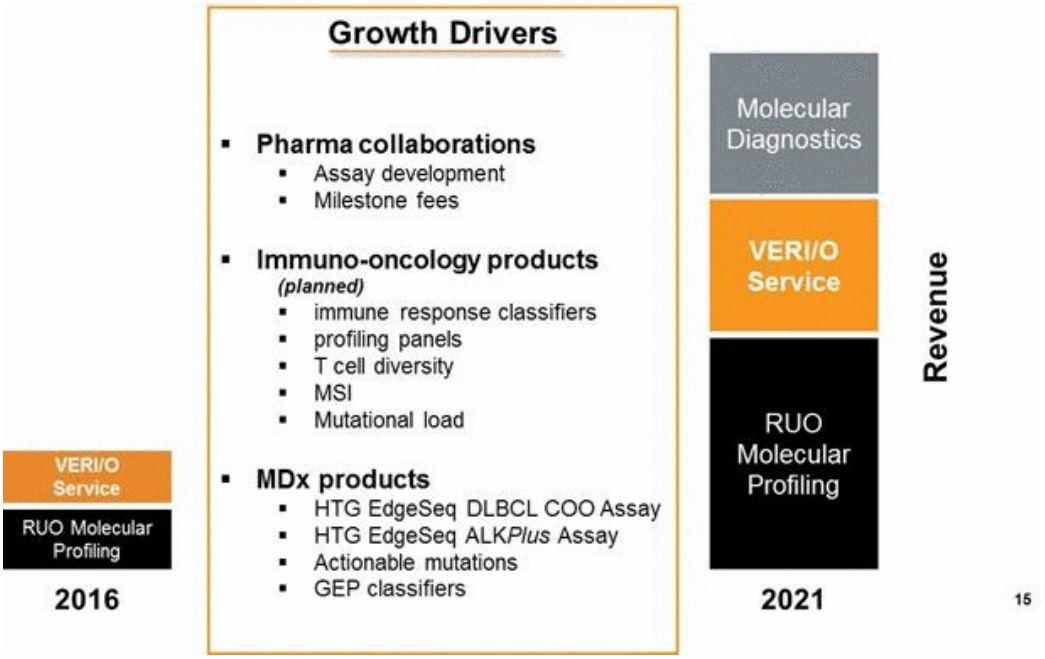
- *HTG EdgeSeq Immuno-Oncology Assay*. One of the most promising areas of cancer therapy is immunotherapy or immuno-oncology, where new classes of oncology drugs are thought to enable or boost the host immune response towards tumors. Multiple drugs targeting the genes *CTLA4, PD-1* and *PD-L1* are on market with additional candidates moving into late-stage trials. Profiling samples for the genes targeted by these therapies may be predictive of drug response and aid in the stratification of patients into responsive and non-responsive groups. The HTG EdgeSeq Immuno-Oncology Assay measures the expression of 549 of these immuno-oncology-associated genes.
- *HTG EdgeSeq DLBCL Cell of Origin Assay*. DLBCL tumors are frequently classified into either the activated B-cell like, or ABC, or germinal center B-cell like, or GCB, sub-types by measuring the molecular profile of the tumor. These two subtypes display different clinical pathologies, as patients with the GCB subtype of DLBCL tend to respond differently than those of the ABC sub-type. With many of the large number of new DLBCL-targeting drugs appearing to have greater efficacy in one of the sub-types, a need for a reliable, FFPE-based cell of origin classification assay has emerged. The HTG EdgeSeq DLBCL Cell of Origin Assay is being utilized in numerous late-stage drug programs to stratify these patients.
- *HTG EdgeSeq Oncology Biomarker Panel*. This RNA expression panel measures the expression of up to 2,560 genes implicated in cancer for profiling tumor tissues, analyzing cancer pathways and identifying new biomarkers across both solid tumors and hematolymphoid neoplasms. We worked with key opinion leaders to identify the genes in this panel, which we believe is a comprehensive list of genes targeting known signaling pathways and receptor gene families implicated in cancer. Representative genes in this panel include EGFR, HER2, HER3, HER4, PD-1 and FGFR. When paired with our HTG EdgeSeq microRNA Whole-Transcriptome Assay (below), we provide customers with a comprehensive solution for profiling their large sample archives for novel expression signatures.

- *HTG EdgeSeq Lymphoma Panel*. Measures the expression of 92 genes frequently assessed in lymphomas, including 22 common non-Hodgkins B-cell lymphoma markers from a single 5 micron thick FFPE section. This product is designed to enable detailed molecular profiles of lymphomas using a single FFPE slide.
- *HTG EdgeSeq microRNA Whole-Transcriptome Assay*. Human microRNAs are short non-coding strands of RNA that are believed to be used by the cell for gene regulation. The HTG EdgeSeq microRNA Whole-Transcriptome Assay enables the simultaneous profiling of 2,083 microRNAs, allowing new, potentially clinically relevant miRNA profiles to be discovered. Our ability to efficiently profile small FFPE samples is a significant differentiator in the rapidly growing microRNA market.
- *HTG Edge DMPK Core CYP Assay*. Biopharmaceutical companies often perform DMPK profiling studies as part of the drug development process to adhere to regulatory guidance. A set of genes known as the cytochrome P450 family is known to predict both the toxicity and stability of drugs in the human body. The HTG Edge DMPK Core CYP Assay enables DMPK scientists to measure six cytochrome P450 genes recommended for *in vitro* pharmacokinetic studies. The DMPK area is a high-volume profiling market segment and creates synergies with down-stream clinical drug development programs.

We utilize several alternative arrangements to sell our systems. Our platforms can be purchased directly by our customers, who also then purchase HTG EdgeSeq assays and other consumables from us on an as-needed basis. In some instances, we provide our instruments free of charge on a limited basis to facilitate customer evaluation. We also may choose to install instruments for our customers at no cost, in exchange for an agreement to purchase assays and other consumables from us at a stated price over the term of the agreement, or allow customers to rent our instrument for a monthly fee. As of December 31, 2016, we had an installed base of 47 HTG Edge and HTG EdgeSeq instruments (consisting of 27 systems sold, six covered under reagent rental agreements, one rental, nine evaluation units and four systems with key opinion leaders).

***Product and Technology Pipeline Plan***

Our objective is to establish the HTG EdgeSeq system as a standard in molecular profiling, making this capability broadly accessible. We are leveraging our flexible and adaptable platform to develop comprehensive molecular profiling panels across an increasing set of molecular applications. We believe it is important to include applications that cover a broad set of genomic variation as well as expression-based clinical biomarkers to continually increase the value of the HTG EdgeSeq system and provide a more complete profiling solution for our customers. The diagram below depicts our planned expansion of systems, applications and profiling panels which are being adding in a phased approach.



***Opportunities for Comprehensive Molecular Profiling in Diagnostics***

We are planning to develop a portfolio of molecular diagnostic products using our proprietary technology to provide a single, efficient testing system for sample profiling that integrates seamlessly into a customer's NGS testing workflow.

We are initially focused on areas where the diagnostic testing paradigm has significant inefficiencies. For example, many leading medical institutions are shifting from a single-drug / single-test approach to a broader tumor profiling strategy for their oncology practices. Rather than testing for single mutational analyses, such as KRAS mutations in colorectal cancer, these institutions use their NGS platforms to assess the mutational status of 50 or more genes. In addition, the information a physician needs to make clinical decisions often comes from tests conducted using various testing modalities such as IHC, FISH and NGS. These complexities lead to a growing and unmet demand in clinical diagnostics for more comprehensive molecular profiles that can include RNA expression, RNA fusions and rearrangements, DNA mutations and protein expression.

We are developing solutions to address the detection and measurement of gene rearrangements such as gene fusions and insertions. A fusion gene is a hybrid gene formed from two previously separate genes. A well-established example is the EML4-ALK fusion gene found in a subset of malignant lung cancers. Our research team previously demonstrated feasibility to simultaneously detect and measure key gene fusions in lung cancer such as ALK, ROS1, RET and NTRK1 from multiple small sample types including FFPE, cell lines and purified RNA. An insertion is the addition of one or more nucleotides into a genomic sequence; a small percentage of NSCLC exhibit HER2 exon 20 insertions.

We are currently developing our HTG ALK*Plus* Assay, or ALK*Plus* Assay, as our first clinical diagnostic test for the U.S. market. Our ALK*Plus* Assay is a comprehensive panel for lung gene rearrangements that will detect certain fusions in the following genes: ALK, ROS1, RET and NTRK1 as well as certain insertions in HER2. This test panel is in clinical study phase and three of the four PMA modules have been submitted to the FDA. We completed the CE marking of this assay in Europe in March 2017, and expect to obtain FDA pre-market approval for the ALK*Plus* Assay by late 2017 or early 2018. The intended use for the ALK*Plus* Assay, if approved by the FDA, will be as a companion diagnostic for crizotinib therapy for ALK positive NSCLC cases. Information on the ROS1, RET, NTRK1 and HER2 gene rearrangements included in the ALK*Plus* Assay panel will be provided with RUO status. After obtaining the appropriate exemption(s), we believe the ROS1, RET, NTRK1 and HER2 gene rearrangements detected with the ALK*Plus* Assay could also be used for investigational use only, or IUO, for certain late-stage drug development trials, and, as appropriate, receive FDA approval in the future.

When we look at the current state of a NSCLC patient assessment, the HTG EdgeSeq ALK*Plus* Assay fulfills one critical part of the current diagnosis process. Other critical factors clinicians need to understand NSCLC prior to treatment are the tumor sub-type (adenocarcinoma, or ADC, squamous cell carcinoma, or SCC, neuroendocrine) and its EGFR and KRAS mutational status. A well-known U.S. cancer center recently published a peer-reviewed article showing that our technology can be used to determine whether a tumor is an ADC or SCC. In addition, we are currently developing enhancements to our chemistry, our V2 chemistry, which we believe will enable direct-sequencing of EGFR and KRAS mutations in NSCLC and other disease states. Taken together, these enhancements could, in the future, provide a single testing workflow, which we refer to as the HTG total lung solution, whereby information about the NSCLC subtype and status of clinically recognized biomarkers can be obtained in a single "multiparameter" test.

Ultimately, we believe that HTG technology can bring multiparameter testing to a wide variety of solid tumor sample types. We will need to develop, refine and implement new panel protocols and make changes or adjustments to our chemistry and software to optimize these planned applications and panels for use with our HTG EdgeSeq system. This will require substantial effort from our research scientists and the use of various laboratory equipment, supplies and materials, which combined represent the most significant costs that we expect to incur in connection with the development of these applications and profiling panels.

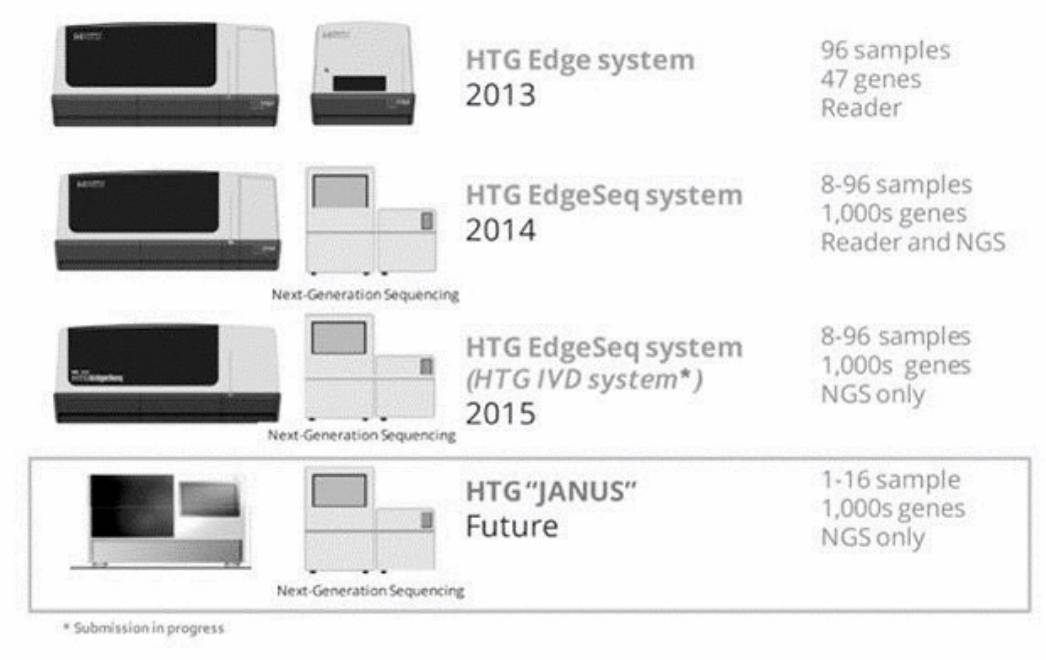
***The HTG EdgeSeq system can augment or, in some cases, replace IHC testing***

IHC tests currently are integral to the diagnostic workup for most tumor types, providing qualitative protein expression data within the morphological context of the tissue tested. While there are over 400 different biomarkers tested by IHC in clinical practice today, we believe it is rare to test more than ten. This is due in part to tissue availability, especially for minimally invasive core needle biopsies, and limitations on the number of tests reimbursed per case. We are in the concept stage for an HTG EdgeSeq next generation pathology product, which is intended to enable the assessment of the RNA analogues for a clear majority of clinical IHC biomarkers in a single NGS-based test. We believe this single-test concept will provide pathologists a standard by which to measure all tumors, augmenting or in some cases replacing their IHC testing with a quantitative assessment of the tumor biology.

***Serving the decentralized markets with Project JANUS***

In addition to continued menu expansion for clinical diagnostic products we have begun the development of our next generation instrument targeting the lower throughput clinical market segment. We refer to this development program as Project JANUS. We believe the lower throughput clinical market segment will potentially increase our addressable market for instrument sales from hundreds to thousands of labs. The molecular testing market is served by a mix of centralized reference laboratories, comprehensive cancer centers, and decentralized regional hospital laboratories. Volumes of particular case types and downstream testing needs for solid tumors are somewhat unpredictable for these providers. We believe Project JANUS is well suited for managing low, medium, and surge testing volumes; thus, assisting our customers with this unpredictable aspect of their businesses. We anticipate testing panels for Project JANUS to include mutations, fusions, expression classifiers and a molecular surrogate for IHC. Our approach is to serve centralized markets with the HTG EdgeSeq system and expand to the decentralized market with Project JANUS, as shown schematically in the following figure. We believe our current HTG EdgeSeq system has the throughput capabilities that match the needs of the centralized market. Project JANUS is our planned approach to expand our addressable market to the lower sample throughput labs and further decentralize the market. Due to various research and development priorities, Project JANUS development efforts were temporarily put on hold during the third quarter of 2016. We intend to resume development efforts as soon as reasonably feasible and as our V2 chemistry matures.

**Our Technology**



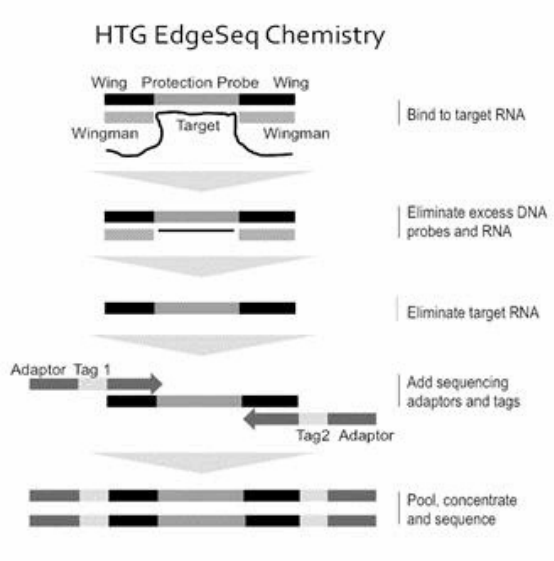

***HTG Chemistries***

The qNPA chemistry used in our current HTG EdgeSeq assays reliably measures tens to thousands of messenger RNA, or mRNA, and microRNA gene expression levels from very small amounts of difficult to handle samples without the need for conducting RNA extraction, cDNA synthesis, RNA amplification or RNA-labeling steps. Two primary elements of our chemistry process are DNA to RNA hybridization and S1 nuclease digestion. Both elements have been widely researched for decades and are well understood. The method is described in more detail below.

*HTG EdgeSeq Chemistry*

Our HTG EdgeSeq chemistry is shown schematically in the following figure. Specifically, DNA nuclease protection probes, or DNA protection probes, which include a target-specific region flanked by universal wing sequences are hybridized to targeted RNAs. Target RNA can be both soluble and cross-linked in the biological matrix. Universal DNA wingmen probes are hybridized to the wings to prevent S1 nuclease digestion. S1 nuclease is added to remove single-stranded nucleic acids, including unhybridized DNA

protection probes and RNA. Following S1 nuclease treatment, the only remaining DNA protection probes in the reaction are those hybridized to targeted RNA and wingmen probes to form a hybridized complex. This produces an approximately 1:1 ratio of DNA protection probes to the RNA targeted in the sample. Alkaline hydrolysis of the hybridized complexes releases the DNA protection probes from such complexes. The released DNA protection probes are ready for quantitation. DNA protection probes are labeled with sequencing adaptors and tags in a thermocycler. The labeled DNA protection probes are concentrated, pooled, and ready for sequencing using standard NGS protocols. Data from the NGS instrument is processed and reported by the parser software provided with the HTG EdgeSeq system.




*HTG EdgeSeq V2 Chemistry*

Like our current HTG EdgeSeq chemistry described above, our next generation V2 chemistry is based upon nuclease protection probes, which are used to protect regions of DNA and/or RNA for direct sequencing of the target. We expect to provide further details about the V2 chemistry in due course. We plan to make our V2 chemistry first available in our VERI/O laboratory, in the first half of 2017, for services such as detection of selected DNA mutations.

*Key Advantages of HTG Chemistries*

- *Multiplexing tens, hundreds or thousands of targets.* Measuring multiple genes in a single reaction can be challenging with competitive technologies due to the complex interactions of reaction components. While we are currently marketing a panel with our HTG EdgeSeq chemistry that can profile up to 2,560 genes in a sample, we believe we can develop applications using our chemistry for multiplexing more than 2,560 genes if there is a customer need. The high level of gene multiplexing allows for significantly lower amounts of tissue to be used per sample than in competitive low-plex profiling technologies.
- *No RNA extraction.* Competitive technologies for assessing RNA generally require RNA that is isolated and purified from other components found in the sample. These time-consuming steps may lead to some target loss and bias the test outcome. In FFPE tissues, for example, it has been reported that a fraction of the RNA is lost in the purification process because it cannot be separated from insoluble tissue components and the fixation and embedding process or long storage times for FFPE tissue may damage the RNA and break it into smaller, more difficult to analyze fragments. This makes molecular profiling of small FFPE tissues particularly challenging and can result in testing failures and loss of precious samples due to insufficient RNA recovery. These biases introduced by RNA extraction cannot be overcome and may be magnified throughout the subsequent analysis. Our proprietary chemistry does not require RNA extraction for FFPE samples or most other sample types (we recommend extracting RNA from fresh-frozen tissue samples to prevent processing variability), improves utilization of precious samples, improving workflow and reducing costs by eliminating a step known to bias the data.

- *No cDNA synthesis.* Many competitive technologies, most prominently qRT-PCR and traditional RNA sequencing, require conversion of RNA into DNA for analysis. This process, called reverse transcription, requires an enzyme to move along the extracted RNA to create a DNA copy of the molecule. When damaged and fragmented RNA is used, these small RNA strands become increasingly difficult to convert into DNA in an accurate and reproducible manner. Our proprietary chemistry does not require conversion of the RNA to DNA by reverse transcription, removing a technical difficulty experienced with competitive technologies.
- *Short protection probes.* Many samples contain RNA degraded by various combinations of heat, age, poor processing, and fixation. In these samples, the RNA is damaged and fragmented into smaller strands. Utilizing short protection probes of 50 bases or less, our proprietary chemistry is more efficient than competitive technologies that require longer strands of RNA for quantitation.
- *Simplicity.* Our proprietary chemistry is simple, with fewer steps than competing technologies. Compared to RT-qPCR, our chemistry does not require extraction or cDNA synthesis. Compared to traditional RNA sequencing, our chemistry does not require extraction, cDNA synthesis, shearing, rRNA depletion, ligation, adenylation, or size selection. We believe that the accumulation of these steps required by other technologies results in amplification of biases, sample degradation and increased opportunities for technician error.

***HTG Chemistry and Instrument Platforms***

Our assays and instruments were developed and are manufactured under ISO 13485:2003 guidelines using our proprietary HTG EdgeSeq chemistry to simplify multiplexed nucleic acid testing in research and clinical laboratories. The entire workflow from sample preparation to a molecular profiling report can be accomplished in approximately 36 hours for 96 samples. With the speed, flexibility, sensitivity, and accuracy of our HTG platforms, combined with the system's ability to work effectively with small sample volumes, researchers can profile tens, hundreds or thousands of different genes per sample.


The HTG Edge and HTG EdgeSeq (shown above) platforms consist of a processor, a host computer and integrated software. The processor is a fully automated instrument that prepares biological samples for quantitation using proprietary, electronically barcoded, single-use consumables. The processor has barcode scanner units to process the two-dimensional barcodes printed on the consumables loaded into the instrument. The barcoded consumables are single-use in order to reduce operator errors and provide chain of custody traceability for the samples. The robotic systems within the instrument are engineered for reliable performance and low maintenance. The walking path of the robot is programmed to minimize any chance of contamination of the reagents or samples. One host computer supports up to five processors allowing laboratories to easily expand their capacity by adding processors.

HTG EdgeSeq applications combine either the HTG Edge processor or HTG EdgeSeq processor with an NGS platform to enable the quantitative analysis of tens, hundreds or thousands of targeted RNAs in a single panel. The sample is prepared for quantitation on the processor, then labeled with molecular sequencing adaptors and tags. The labeled samples are concentrated, pooled, and sequenced on an NGS platform using standard protocols. Data from the NGS instrument are processed and reported by the parser software included with the system. HTG EdgeSeq assays currently are available to process sample batches ranging from eight to 96.

*HTG Edge and HTG EdgeSeq Platform Workflow*

Our HTG platforms deliver complex molecular profiling information in a simple four step workflow. A technician spends relatively little time preparing samples which are easily loaded into the applicable processor. Once the sample is loaded, the processor

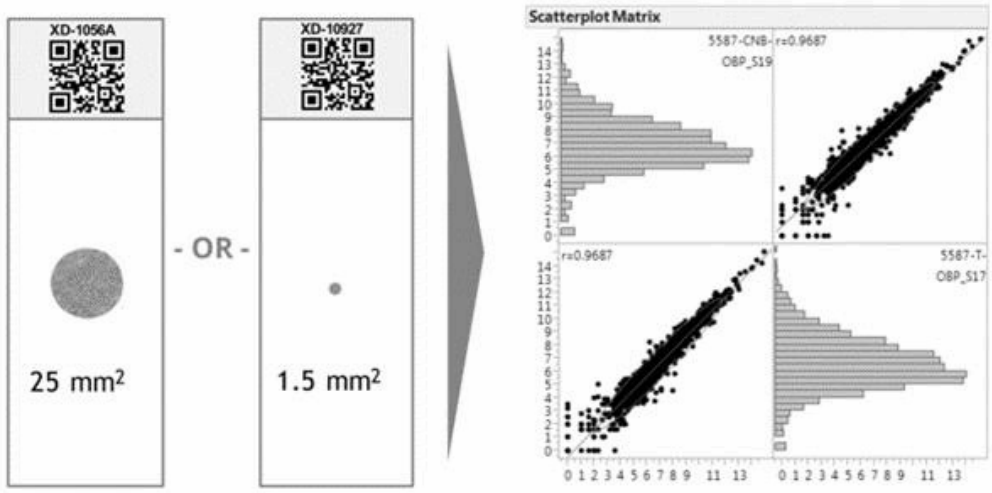
performs our proprietary chemistry protocol with no technician intervention, which is commonly referred to as walk away automation. Once the sample is processed, a technician prepares the sample for quantitation on an existing NGS instrument. This flexibility in quantifying molecular information provides customers the ability to optimize their use of the HTG Edge or HTG EdgeSeq platform based on their specific throughput, workflow and application requirements. In comparison to traditional RNA sequencing (sometimes referred to as RNA Seq), there are many fewer steps required for molecular profiling using HTG EdgeSeq applications as shown in the diagrams below.

*HTG Platform Performance*

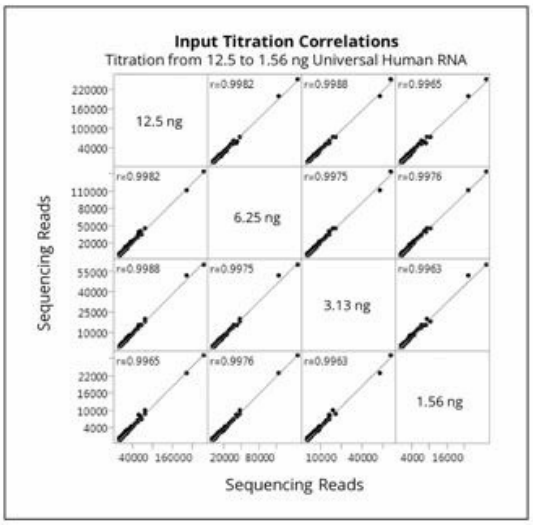
Our HTG systems have performance characteristics that enable our customers to reproducibly, accurately and quantitatively profile from tens to thousands of genes in a single reaction using very small samples. This section provides details and examples of these performance characteristics.

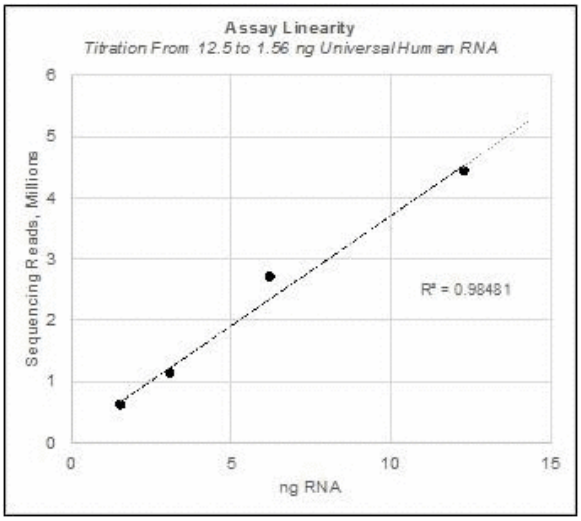
*Equivalent quantitative expression results from large as well as very small samples*

HTG EdgeSeq assays and panels are analytically validated with sample inputs ranging from as much as 25 $mm^2$ to, in a few cases, 1.5 $mm^2$ tumor surface area from a single 5 µm section, enabling comprehensive molecular profiling on a large surgical resection or very small needle core biopsy. Needle core biopsies are often the only tissue available for profiling of certain tumor types. A representation of the difference in the amount of tissue available in a surgical resection versus a core needle biopsy is shown graphically below (left panel). In an internal study using our HTG EdgeSeq resections versus core needle biopsies from the same non-small cell lung cancers (right panel), Pearson correlations (log2 transformed counts) greater than 0.96 were observed. These results indicate that our assay provides the same result for the two sample sizes tested.



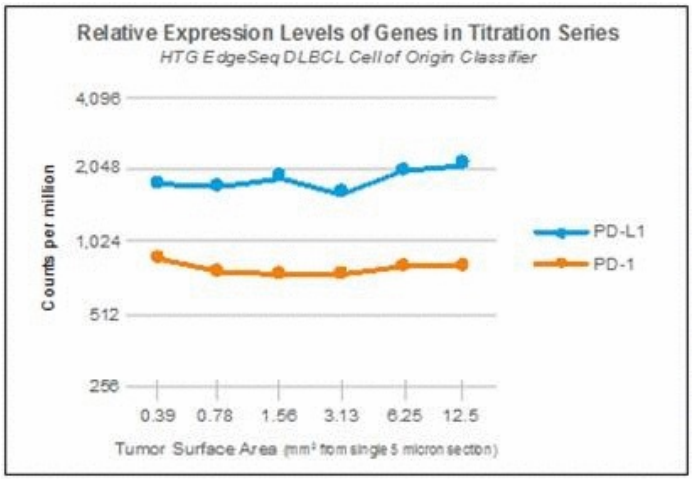
We believe obtaining molecular profiles from very small samples is of critical importance to our customers. We have demonstrated reproducible, quantitative results from a fraction of the more than 100 ng of input RNA typically required for competitive technologies. In the study shown below, the HTG EdgeSeq Oncology Biomarker Panel was used to measure mRNA expression levels in a dilution series from 12.5 ng to 1.56 ng of Universal Human RNA. In the figure titled Input Titration Correlations below, correlations between each dilution were measured by Pearson's r and are displayed in each comparison field. A Pearson correlation between two perfectly identical molecular profiles will produce an r-value of 1.0. The r-values obtained in the study shown below, of greater than 0.99, indicate nearly identical molecular profiles were obtained throughout the dilution series. In the figure titled Assay Linearity below, the raw number of sequencing reads for each of the samples in the dilution series are shown, with the statistical measure of how close the data are to the fitted regression line, R-squared, of 0.98481. These plots demonstrate the capability of the HTG EdgeSeq applications on the HTG Edge or HTG EdgeSeq platform to deliver equivalent molecular profiles over a range of sample inputs.



*Leveraging the dynamic range and sensitivity of NGS*

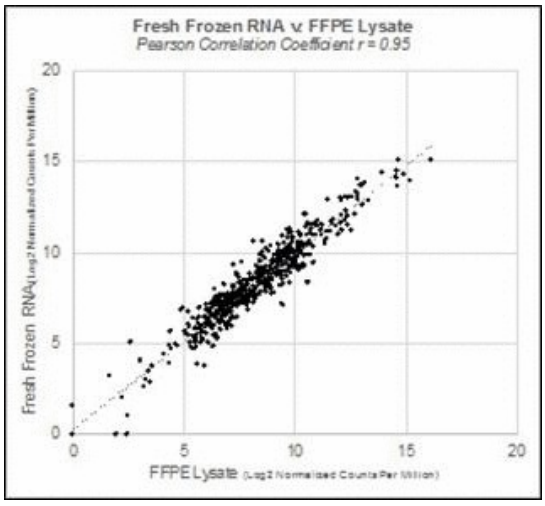
The end product of the HTG EdgeSeq assay is a library of DNA probes that, once sequenced, are compared to a reference database consisting of the sequences of the probes used in the assay. NGS platforms sequence each nucleotide of each DNA probe in the library to produce highly specific information about each such probe. Each nucleotide sequenced is stored as a single read. With the capacity of a single sequencing run numbering in the millions of reads, NGS platforms are highly sensitive, capable of detecting low abundance or rare sequences, while having a wide dynamic range, accurately counting the relative number of abundant sequences. In the development and validation of gene expression assays, we believe it is important that the applicable assay reliably measure differential gene expression for both high and low abundance genes. As an example of how the HTG EdgeSeq system leverages the sensitivity of NGS, the graphic below shows the relative expression of the low-abundance immunotherapy targeted genes PD-1 and PD-L1 across a wide range of sample inputs using the HTG EdgeSeq DLBCL Cell of Origin Assay.




*High fidelity between processing conditions*

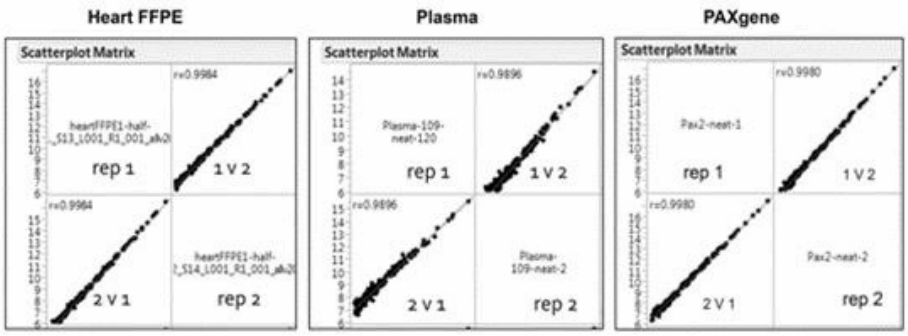
One of the greatest challenges faced in molecular profiling of formalin fixed samples is the poor fidelity routinely seen when comparing the results across various processing conditions. One example is the lack of fidelity seen between formalin fixed samples, such as FFPE, to non-fixed tissue. It has been repeatedly demonstrated that the fixation process can lead to different molecular profiles in otherwise identical samples. We believe researchers often obtain sub-optimal molecular profiling results solely due to the formalin fixation process. We further believe that our chemistry overcomes the losses in fidelity between non-fixed and FFPE tissues, enabling users to obtain an accurate assessment of tumor biology from FFPE tissues.

To demonstrate fidelity between non-fixed and FFPE tissues that may be achieved using the HTG EdgeSeq system, a resection from a breast cancer tumor was prospectively collected and split, with half of the specimen immediately frozen and the other formalin fixed and paraffin embedded. RNA from the non-fixed, fresh frozen specimen was extracted and added to the HTG lysis buffer (we recommend extracting the RNA from fresh tissue samples to prevent processing variability). The matched FFPE tissue was directly lysed in the HTG lysis buffer without extraction. Both specimens were then profiled using the HTG EdgeSeq Immuno-Oncology Assay. The scatterplot below shows the correlation between the non-fixed, fresh frozen tissue and the FFPE tissue, with a Pearson correlation coefficient of r = 0.95, indicating that our proprietary chemistry produces the same result regardless of whether or not a sample is fresh or fixed. We believe our system enables researchers and clinicians to access their large collections of archived FFPE tissues to deliver reproducible, biologically relevant molecular profiles.




*Compatibility with multiple sample types*

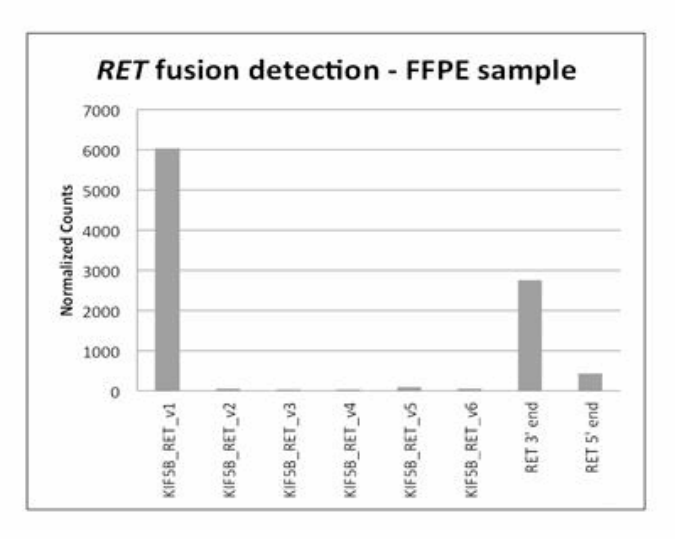
We believe our proprietary chemistry is robust across many biological sample types. Below are technical replicates of heart FFPE, plasma and whole blood preserved in PAXgene profiled using the HTG EdgeSeq microRNA Whole-Transcriptome Assay. As shown by the high correlations, our customers can expect the same result from a sample run after run.



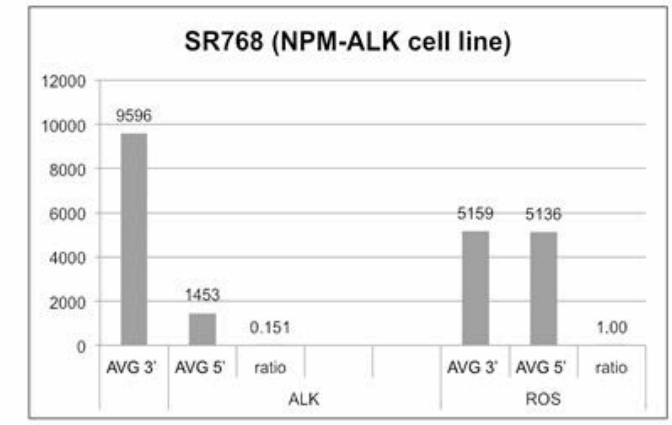

*Detection of gene fusions*

In feasibility studies, HTG EdgeSeq chemistry has demonstrated the ability to accurately detect gene rearrangements in patient-derived FFPE tissues. The example below demonstrates detection in a patient sample with a characterized gene fusion involving the KIF5B and RETS genes. Using multiple DNA protection probes, the HTG EdgeSeq system can detect gene rearrangements such as fusions. We are developing an assay that allows gene fusions to be detected in two ways. First is the direct measurement and detection of the unique RNA sequence created at the gene fusion site. This is indicated by the strong signal obtained from the KIF5B-RET v1 probe in the following graph. The second approach involves calculating the ratio of signals obtained from probes targeting both the 5' and 3' end of the RET gene. Samples which do not contain a RET gene fusion will have similar RET 5' and RET 3' expression. In the

sample above, however, which contains a RET gene fusion as indicated by the fusion-junction specific prove, we see significantly higher signal from the RET 3' probe implying the two parts of the RET gene are no longer connected, indicating a gene rearrangement has occurred.

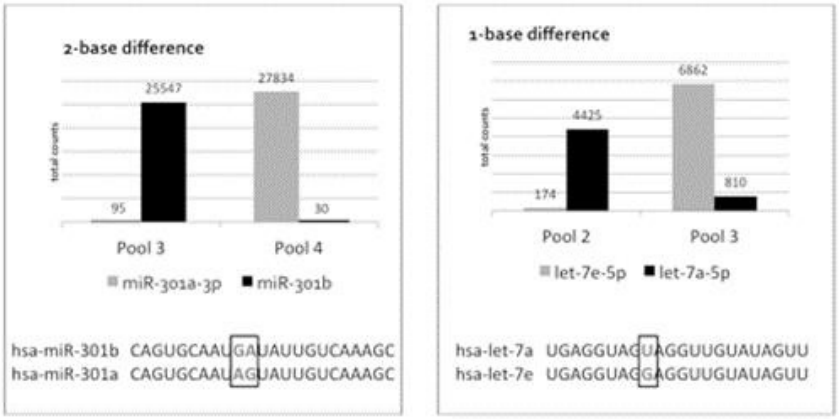



A cell line with a known ALK gene fusion and normal (or wild-type) ROS1 gene was tested using the same 5' and 3' probe ratio methodology described for the RET fusion above. As expected with a fused ALK gene, the expression of the 3' portion of the transcript is much higher than the 5' portion, indicating a fusion event has occurred. An example of a known non-fusion gene, ROS1, is also shown in the example where the 5' and 3' ends of the ROS1 are expressed at a 1:1 ratio, indicating this gene has not undergone a fusion event.



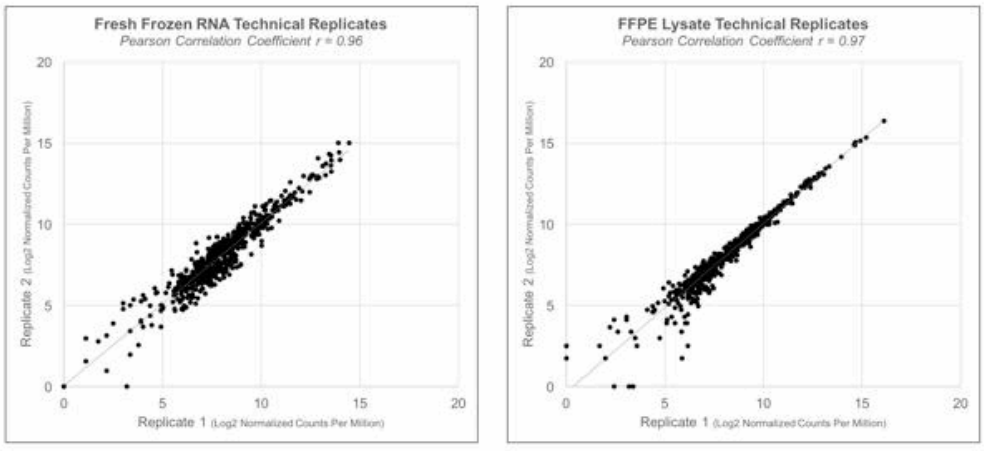
*Discriminating between closely related sequences*

The specificity of our proprietary chemistry is demonstrated in the data chart below. Closely related synthetic miRNA pools supplied by Association of Biomolecular Resource Facilities were split between pools. All possible probes were used to profile individual pools. As shown in the following graphs, from 3-11% of NPP probes bound to off-target sequences with a 1-base difference (right graph) while only 0.1-0.3% of NPP probes bound to off-target sequences with a 2-base difference (left graph). In both examples, the on-target hybridization signal is at least 8X greater than off-target hybridization. Data was generated using the Illumina MiSeq v2 1x50 reagent kit. We believe that our proprietary chemistry is highly specific and will enable our customers to discriminate between closely related sequences.



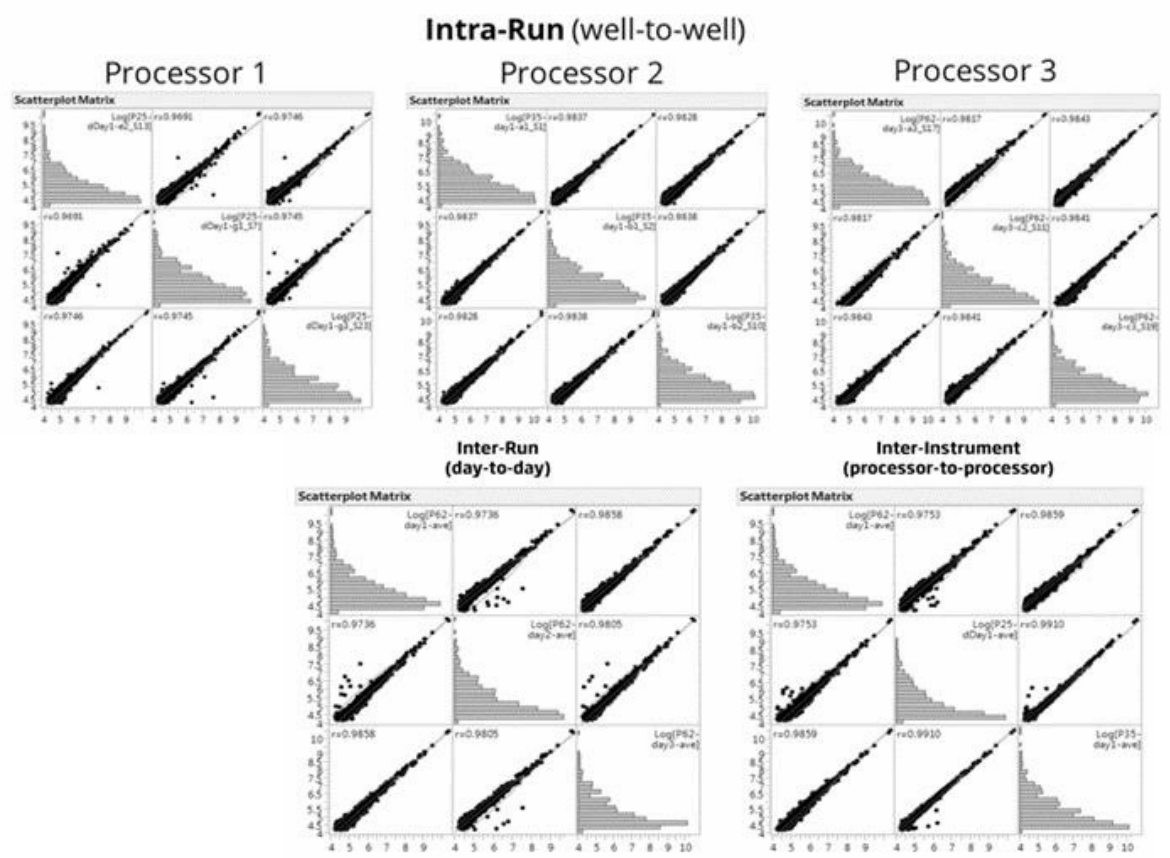

*Repeatability*

An important consideration in adoption of a molecular profiling platform is the degree to which the same molecular profile can be obtained from a sample tested on multiple replicates and multiple occasions. Obtaining highly similar profiles indicates that the panel is stable, and that the data generated is reliable and repeatable. The XY scatterplots below show the correlation between the same sample on technical replicates using the HTG EdgeSeq Immuno-Oncology Assay. Extremely similar results were obtained, as demonstrated by the Pearson correlation coefficient r-values of 0.96 and 0.97 for fresh frozen and FFPE samples, respectively. We believe the HTG EdgeSeq system enables our customers to produce stable and repeatable molecular profiles. As demonstrated by the measurement of 549 mRNAs in the sample, HTG EdgeSeq chemistry has the ability to reliably detect large numbers of genes in a complex background.



*Reproducibility*

Another important consideration in adoption of a molecular profiling platform is the degree to which the same molecular profile can be obtained from a single sample tested multiple times over on the same and different instruments. Obtaining highly similar profiles indicates that the chemistry and instrument platform is stable, and that the data generated is reliable and reproducible. The XY scatterplots below show the correlation between the same sample profiles on three separate instruments across three days using the HTG EdgeSeq Oncology Biomarker Panel. The scale of the vertical and horizontal axes represent log 2 transformed, filtered probe counts. Extremely similar results were obtained, as demonstrated by the Pearson r-values above 0.96 for all comparisons. We believe the HTG EdgeSeq platform and HTG EdgeSeq chemistry enables our customers to produce stable and reproducible molecular profiles.




**Research and Development**

We have committed, and expect to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled an experienced research and development team with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. As of December 31, 2016, our research and development team consisted of 21 employees across the disciplines of research and development scientist, platform development and bioinformatics.

As discussed in more detail above, in addition to an ongoing focus on the expansion of our profiling applications and test panel menu, in 2016 we began the development of the next generation of our HTG EdgeSeq chemistry, or V2 chemistry, which will allow targeted, direct sequencing of RNA and DNA. Applications of the V2 chemistry are likely to include mutation detection, expressed mutation detection, expression measurements and co-detection of RNA and DNA from FFPE tissue.

We have also begun the development of our next generation Project JANUS instrument program. External development efforts for Project JANUS with Invetech PTY, Ltd. were temporarily put on hold in mid-2016, but are expected to resume in the near future as our V2 DNA chemistry matures.

We incurred research and development expenses of $7.9 million and $4.6 million for the years ended December 31, 2016 and 2015, respectively.

**Sales and Marketing**

We distribute our instruments and consumables via direct sales in the United States and Europe and also through distributors in parts of Europe and other countries. As of December 31, 2016, our U.S. sales and marketing organization consisted of 33 employees including 11 in direct sales or sales management, 15 in sales support and seven in marketing. In addition to our direct sales team in the United States, as of December 31, 2016, we had three direct sales and support employees in Europe and distribution agreements in several additional countries. This sales model provides us with direct sales coverage in the United Kingdom, France, Germany, Switzerland, Belgium and the Nordic countries, and distributors in Spain, Portugal, Italy and Israel.

Our sales and marketing efforts are targeted at biopharmaceutical companies, clinical research centers and clinical diagnostic labs focused on sample profiling for translational research, biomarker/companion assay development and lab-developed diagnostic testing. We intend to promote adoption of our HTG EdgeSeq system, sample profiling panels and future molecular diagnostic assays, upon marketing clearance or approval by FDA by expanding our U.S. sales force, building a greater direct sales presence in Europe, expanding international distribution, and continuing to collaborate with key opinion leaders to validate our platform and influence utilization of our products.

The top two customers accounted for 29% and 12% of our revenue for the year ended December 31, 2016, compared with 38% and 7% for the year ended December 31, 2015. We derived 0% and 8% of our total revenue from grants and contracts primarily from one organization during the years ended December 31, 2016 and 2015, respectively.

**Manufacturing and Suppliers**

We primarily perform manufacturing and final acceptance testing in house. External resources are leveraged for their specific expertise in either producing components for our HTG Edge and HTG EdgeSeq instruments and raw materials for our consumables in accordance with our designs, or based on their catalog products which are utilized as is within our designs. We manufacture HTG Edge and HTG EdgeSeq instruments and reagent kits at our Tucson, Arizona facility, which has been certified to ISO 13485:2003 standards. We completed capital improvements in 2016, which created over 6,500 square feet of dedicated manufacturing and operations space. We believe that our existing manufacturing capacity is sufficient to meet our needs at least for the next several years.

***Instruments***

We assemble our HTG Edge and HTG EdgeSeq instruments at our Tucson, Arizona facility. We have qualified an alternative third-party manufacturer for our instruments and we believe additional instrument manufacturing alternatives would be available if necessary. Instrument component vendors are qualified and reviewed regularly to ensure that manufacturing standards are met and maintained. We award contracts for estimated annual quantities of components and, considering the replenishment lead times of our vendors, take delivery of batches covering approximately one month of demand at a time.

***Consumables***

We assemble our HTG Edge and HTG EdgeSeq consumables at our Tucson, Arizona facility. Raw material vendors are selected using precise standards, and are reviewed regularly for compliance with our specific quality requirements. We purchase raw material stock in quantities that often exceed projected annual demand. We complete batches of finished goods approximating quarterly demand and supervise inventory on a minimum/maximum basis to ensure that we are replenishing our finished goods and raw material ahead of demand.

**Competition**

We have categorized known competition into:

- Other molecular platform offerings such as PCR-based technologies, microarrays and next generation sequencers from companies such as Agilent Technologies, Inc., ArcherDx, Inc., BioRad Laboratories, Exiqon A/S, Fluidigm Corporation, Genomic Health, Roche Diagnostics, a division of the Roche Group of companies, QIAGEN, Illumina, Inc., Abbott Molecular, Luminex Corporation, Affymetrix, Inc., NanoString Technologies, Inc. and Thermo Fisher Scientific, Inc.
- Centralized CLIA labs offering molecular profiling and gene expression tests as laboratory-developed tests, or LDTs, such as Foundation Medicine, Inc., Trovagene, Inc., Guardant Health, Inc. and Genomic Health, Inc.
- NGS target enrichment technologies from companies such as Agilent Technologies, Inc.
- Decentralized CLIA labs developing LDTs locally such as major cancer centers

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 product

We believe the automation afforded by our HTG EdgeSeq system coupled with fast turnaround time, high multiplexing capability, lysis only/no extraction protocol and low sample requirement gives us numerous competitive advantages in our target markets, as discussed in more detail elsewhere in this Item 1.

While we believe that we compete favorably based on the factors described above, many of our competitors are more highly capitalized and/or have been in existence for a longer period, and enjoy several 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.

**Intellectual Property**

Our success depends in part on our ability to develop and maintain intellectual property rights relating to key aspects of the technology employed in our HTG Edge and HTG EdgeSeq platforms and assays, maintain any strategic licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We rely upon certain patents, registered and common law trademarks, trade secrets, know-how, invention and patent assignment agreements and continuing technological innovation to develop and maintain our competitive position. We intend to aggressively protect, defend and extend the intellectual property rights in our technology.

***Patents and Patent Applications***

As of December 31, 2016, our patent portfolio included 13 patent families that, collectively, consisted of nine issued U.S. patents, 37 granted foreign patents (variously in Australia, Canada, China, Japan, France, Germany, Italy, Spain, and United Kingdom), and 28 patent applications pending in the United States and foreign jurisdictions. This portfolio is directed to our nuclease-protection-based technologies as well as to lung cancer and melanoma biomarker panels and a DLBCL cell-of-origin classifier discovered using our nuclease-protection-based technology, which will help us maintain an exclusive position in key areas of our business, including targeted nuclease-protection based sequencing, and, if we should so elect, may provide opportunities for out-licensing melanoma, DLBCL, or lung-cancer-related content. There were two pending applications and 10 granted patents, including one U.S. patent, directed to our novel HTG EdgeSeq methods in the portfolio as of December 31, 2016. The HTG EdgeSeq method patents will expire in April 2032. The portfolio also included two pending applications directed to our V2 HTG EdgeSeq methods as of December 31, 2016. Worldwide, as of December 31, 2016, we had 21 patents in the two patent families directed to our HTG Edge plate-based methods; these patents will begin to expire at the end of December 2017 with the last ones expiring in June 2022.

***Agreements with Third Parties***

*Asset Purchase Agreement with NuvoGen Research, LLC*

We entered an asset purchase agreement dated January 9, 2001, as amended in November 2003, September 2004, November 2012 and February 2014, with NuvoGen to acquire certain intellectual property from NuvoGen. The acquired technology generally relates to our array-based nuclease protection panels. Pursuant to the terms of the agreement, in exchange for the acquired technology, we initially paid NuvoGen 5,587 shares of our common stock, fixed payments of $740,000 over the first two years of the agreement and agreed to pay NuvoGen 6% our yearly revenue, which would be applied to any fixed payments, until the total aggregate cash compensation paid to NuvoGen under the agreement equals $15,000,000. Pursuant to the latest amendment to the agreement, through 2017, we are only required to pay a yearly fixed fee, in quarterly installments, to NuvoGen of $800,000, and may defer any accrued revenue-based payments. Beginning in 2018, we are obligated to pay the greater of $400,000 or 6% of sales, plus amounts, if any, deferred in the 2017 period by which 6% of revenue exceeds the applicable fixed fee plus 5% interest on such deferred amounts until the obligation is repaid in full. We paid our fixed fees for 2015 and the first quarter of 2016 in advance, and resumed making quarterly payments in April 2016. No revenue-based payments were deferred in 2016.

In a transaction related to the foregoing acquisition, NuvoGen also received a non-exclusive, royalty free license under the acquired technology pursuant to an agreement dated September 15, 2004. The license is limited to NuvoGen's own internal service-oriented efforts and activities to accelerate the development of targeted drugs and other pharmaceutical compounds and agents as part of NuvoGen's grant funded or other basic research and development of drugs intended for the treatment of cancer. Pursuant to the agreement, if NuvoGen produces revenue through the sale of cancer drugs developed through use of the license for entities other than for-profit and other commercial drug-research and development service ventures, NuvoGen will pay us a royalty in the mid-single digit range percentage of such revenue for the quarter. This agreement may be terminated by either party in case of a breach by the other party, and we may terminate the agreement by giving written notice if NuvoGen files for bankruptcy or performs other similar actions.

*License Agreement with Merck*

In connection with the investment by Merck Capital Ventures LLC in the Company, we granted to Merck Sharpe & Dohme, or Merck, pursuant to an agreement dated February 15, 2011, a non-exclusive, worldwide, royalty-free, non-sublicenseable (except to affiliates of Merck) license to certain of our qNPA patent rights solely for Merck's internal research and development purposes. We may terminate the agreement upon a breach of any material provision of the agreement by Merck, if Merck has not cured such breach within 60 days after receiving written notice from us.

*Loan and Security Agreement with Oxford Finance, LLC and Silicon Valley Bank*

On August 22, 2014, we entered a Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford, as collateral agent, or in such capacity, Agent, and a lender and Silicon Valley Bank, as a lender, or SVB, and together with Oxford, the Lenders, providing for up to two separate term loans in an aggregate principal amount of $16.0 million.

We borrowed the initial term loan in the principal amount of $11.0 million, or Term Loan A, on August 22, 2014. Term Loan A bears interest at a fixed rate of 8.50% per annum. On or prior to June 30, 2015, the Loan Agreement allowed us to borrow one additional term loan, or Term Loan B, for up to $5.0 million, subject to the satisfaction of certain borrowing conditions. We received the Term Loan A proceeds, net of a $320,000 original issue discount, with a requirement to pay a final payment of 3.75% of the total amount borrowed.

In August 2015, the Company and its lenders amended the Loan Agreement to extend the availability of Term Loan B until March 31, 2016. Pursuant to the August 2015 amendment to the Loan Agreement, we made monthly interest-only payments until April 1, 2016. Following the interest-only payment period, equal monthly payments consisting of principal and interest amortized over the remaining term of the loan through the September 1, 2018 maturity date are due. The amendment also increased the final fee payment percentage to 4.75%. In February 2016, the Company notified its lenders, pursuant to the requirements of the amendment to the Loan Agreement, of its intention to draw the remaining $5.0 million available under Term Loan B. This additional principal will be repaid evenly over the course of 30 months beginning April 1, 2016 and bears interest at a fixed rate of 8.75%. The final fee premium relating to Term Loan B of $237,500 is being amortized to interest expense, using the effective interest method, over the term of Term Loan B.

We may prepay all, but not less than all, of the loaned amount plus accrued and unpaid interest thereon through the prepayment date with 15 days' notice to Oxford. In accordance with the August 2015 amendment, we will be obligated to pay a prepayment fee equal to (i) 2% of the principal amount repaid if the loan is prepaid after the first anniversary but on or prior to the second anniversary of the August 2015 amendment and (ii) 1% of the principal amount repaid if the loan is repaid after the second anniversary of the August 2015 amendment and prior to maturity. We are not entitled to reborrow any amounts of principal once such principal has been repaid. The agreement was again amended in June 2016 to modify 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.

While any amounts are outstanding under the credit facility, we are subject to several affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. We are also restricted from paying cash dividends or making other distributions or payments on our capital stock except for repurchases of stock pursuant to employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed $100,000 in the aggregate per fiscal year.

We granted the Agent a security interest in our personal property to secure our obligations under the loan agreement. The security interest does not extend to patents, trademarks and other intellectual property rights (except for rights to payment related to the sale, licensing or disposition of such intellectual property rights) or certain other specified property. If we default under our term loan, our lenders could foreclose on our assets, including substantially all of our cash, which is held in accounts with our lenders.

Upon the occurrence of certain events, including but not limited to the failure by us to satisfy our payment obligations under the loan agreement, the breach of certain of our other covenants under the loan agreement, and the occurrence of a material adverse change, the Agent will have the right, among other remedies, to declare all principal and interest immediately due and payable, and will have the right to receive the final payment fee and, if the payment of principal and interest is due prior to maturity, a prepayment fee. The Agent also will have the right, among other remedies, to foreclose upon and/or sell or otherwise liquidate our personal property upon the occurrence of certain events.

In connection with Term Loan A, we granted each of the Lenders warrants to purchase 1,256,281 shares of the Company's Series E Preferred Stock at an exercise price of $0.2189 per share. The warrants are exercisable until August 22, 2024 and were automatically converted to warrants for common stock upon completion of our initial public offering, or IPO, in May 2015. In connection with the funding of Term Loan B, in March 2016, we issued Oxford a common stock warrant exercisable for 45,307 shares of common stock at an exercise price of $2.759 per share, and the warrant previously issued to SVB 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 Loan Agreement.

*Development and Component Supply Agreement with Illumina, Inc.*

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

In the fourth quarter of 2015, we and Illumina agreed to a development plan for the development and regulatory approval of the selected IVD test kit, following which we paid Illumina a $100,000 fee. Illumina has agreed to provide development and regulatory support as part of the plan, which relates to our HTG EdgeSeq ALK*Plus* Assay, now in development. We are also required to pay Illumina up to $1.0 million in the aggregate upon achievement of specified regulatory milestones relating to the IVD test kits. In addition, we have agreed to pay Illumina a single digit percentage royalty on net sales of any IVD test kits that we commercialize pursuant to the agreement. Ongoing research and development costs for these programs have been expensed as incurred.

Pursuant to the agreement, we have agreed to obtain our requirements for certain components to be used in the development and/or commercialization of IVD test kits from Illumina. We and Illumina have also agreed to negotiate in good faith to enter into a supplemental supply agreement for the continued purchase and supply of the foregoing components.

Absent earlier termination, the agreement will expire in October 2019 or on the date which the last to expire development plan under the agreement is completed, whichever is earlier. We 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 we undergo certain changes of control or immediately if we fail to select a testing field for an IVD test kit within 24 months following the date of the agreement. 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.

*Authorization, Supply and Regulatory Authorization Agreement with Life Technologies Corporation*

In March 2016, we entered an Authorization, Supply and Regulation Authorization Agreement with Life Technologies Corporation, or LTC, a wholly owned subsidiary of Thermo Fisher Scientific, Inc., for the development and worldwide commercialization by us of up to five RNA-based NGS panels, or HTG Assays, for use with LTC's sequencing instruments and components supplied to end-users by LTC.

Pursuant to the agreement, we have agreed to obtain our requirements for certain components to be used in the development of HTG Assays from LTC. In March 2016, we purchased approximately $250,000 of LTC products and equipment in accordance with this agreement. LTC has agreed to provide support in our efforts to obtain regulatory approval of the HTG Assays. We are required to pay LTC a milestone payment in the mid-six figure dollar range upon certain regulatory achievements for each HTG Assay. In addition, we have agreed to pay LTC a single digit percentage royalty on net sales of HTG Assays that we commercialize pursuant to the agreement. No milestone or royalty payments have been accrued or made pursuant to this agreement as of December 31, 2016.

Absent early termination, the initial term of the agreement will expire in March 2021 and thereafter will automatically renew for additional two year periods for as long as we continue to develop or sell HTG Assays, provided that neither party provides written notice of its election to terminate the agreement at least 60 days prior to expiration of the then-current term. Either party may 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 may violate any regulatory law, or any other applicable law or regulation or FDA guidance.

*Bristol-Myers Squibb Agreement*

In May 2016, we entered into a Collaboration Agreement with Bristol-Myers Squibb, or BMS, for the development, in collaboration with BMS, of two custom assays based on our HTG EdgeSeq technology. Following development of each custom assay, at BMS's request, we 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, we will supply custom assay kits and perform sample processing services.

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.

*Merck KGaA Agreement*

In October 2016, we entered a Master CDx Agreement, or master agreement, with Merck KGaA, Darmstadt, Germany, or Merck KGaA to serve as the basis for one or more project agreements to develop, seek regulatory approval for, and commercialize companion diagnostics for Merck KGaA drug candidates and corresponding therapeutics. Concurrently, we entered into a first project agreement under the master agreement concerning our sequencing-based DLBCL cell of origin assay, or DLBCL Assay and Merck KGaA's investigational drug, M7583, or Project.

The Project has three stages aligned with timelines and outcomes of M7583 development. During stages 1 and 2, we will perform specified DLBCL Assay development activities. In stage 3, we will obtain applicable regulatory approvals on the DLBCL Assay and make it commercially available in the United States and certain other jurisdictions.

Stages 2 and 3 each have an up-front payment, and all stages of the Project have milestone-based payments. We are eligible to receive up to a total of $9,900,000 over a period of approximately nine years in fixed or determinable contract consideration comprising up-front and milestone payments. In addition, during stages 1 and 2 of the Project, we will sell DLBCL Assay kits and/or perform sample processing services upon request of, and as instructed by, Merck KGaA.

Merck KGaA may terminate the Project by providing 90 days' prior written notice, at which point Merck KGaA will reimburse us for costs incurred during the termination period, of an amount not to exceed non-cancellable, non-reimbursable expenses, and we will reimburse Merck KGaA for any costs that have been prepaid without being incurred prior to termination. Further, either party may also terminate the agreement upon the other party's material breach that remains uncured for 45 days or upon the other party's bankruptcy.

*QIAGEN Agreement*

In November 2016, we entered a Master Assay Development, Commercialization and Manufacturing Agreement, or Governing Agreement, with QIAGEN Manchester Limited, or QML, a wholly owned subsidiary of QIAGEN N.V. The Governing Agreement creates a framework for the companies to combine their technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays. Under the Governing Agreement, the parties will jointly seek companion diagnostic programs with biopharmaceutical companies, QML will contract with interested biopharmaceutical companies for specified projects, each a Project, and the companies will enter into a statement of work under the Governing Agreement, which sets forth the rights and obligations of each party with respect to each Project.

The parties' relationship under the Governing Agreement is exclusive in the oncology field. Such exclusivity in the oncology field may be lost and become non-exclusive if certain performance targets are not met. Projects may be undertaken in non-oncology fields at each party's discretion on a non-exclusive basis.

The companies will share net profits under each statement of work, based on whether development of particular assays under a statement of work are primarily based on each company's intellectual property. Each statement of work will provide additional financial terms for the corresponding Project, which terms will depend on the respective development and/or commercialization activities of the parties.

The Governing Agreement will continue for a five-year term. However, either party may terminate the agreement upon (i) the other party's uncured material breach, bankruptcy or insolvency, (ii) specified events affecting all statements of work, or (iii) a change of control by either party. In the event a party terminates the Governing Agreement for its own change of control, a $2.0 million termination payment will be payable to the non-terminating party.

Pursuant to a stock purchase agreement, entered concurrent with the Governing Agreement, QIAGEN North American Holdings, Inc., or QNAH, another wholly owned subsidiary of QIAGEN N.V., purchased 833,333 shares of our common stock on November 17, 2016 at $2.40 per share, for a total purchase price of $2.0 million. QNAH agreed to purchase up to an additional $2.0 million of our common stock (subject to any applicable limitations under the rules of the NASDAQ Stock Market) upon the sale by the Company of at least $12.0 million of common or preferred stock in a financing transaction that occurs prior to May 16, 2017, or such other mutually agreeable date, or a Qualified Financing. The price per share payable by QNAH in a second tranche purchase will be equal to the price per share at which shares are sold in a Qualified Financing.

***Trade Secrets***

We also rely on trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. We cannot provide any assurance, however, that we have entered into such agreements with all relevant parties, or that these parties will abide by the terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

For additional information relating to the risks associated with our intellectual property position see "Risk Factors – Risks Related to our Intellectual Property."

**Third-Party Coverage and Reimbursement**

Clinical laboratories will acquire our instrumentation through a capital purchase, capital lease or reagent purchasing agreement. These laboratories will offer their customers a menu of testing services using our IVD test kits or their LDTs, which they may develop using components they purchase from us, or a combination of both. Our customers will generate revenue for these testing services by collecting payments from third-party payors, including public and private payors, as well as patient co-payments.

***United States***

In the United States, our customers will utilize the existing reimbursement framework for testing services: *Tier 1 and Tier 2 Molecular Pathology Procedures*

Prior to January 1, 2013, molecular pathology procedures were reimbursed using the 83890-83912 code series, commonly known as "stacking codes", which were based on the various technical steps performed to produce a test result. The American Medical Association, or AMA, created the Tier 1 codes (81200-81383) and Tier 2 codes (81400-81408) to specifically identify the test being performed and as a replacement to stacking codes. The stacking codes were deleted from the clinical laboratory fee schedule used by the Centers for Medicare and Medicaid Services, or CMS, for payment determination in 2013. Single analyte tests for mutations and gene rearrangements are described by these Tier 1 and Tier 2 codes; specific examples include 81235 for epidermal growth factor receptor, or EGFR, mutation analysis and 81401 for EML4/ALK rearrangement analysis. Single analyte tests not specifically called out in Tier 1 or Tier 2 codes can be submitted for reimbursement consideration using the miscellaneous code 81479.

*Genomic Sequencing Procedures.*

The AMA created codes for Genomic Sequencing Procedures, or GSPs, and other Molecular Multianalyte Assays as part of its calendar year 2015 update to the clinical laboratory fee schedule. AMA has since modified the GSP codes to clarify the definition to include DNA and RNA. Our customers may use these codes to seek reimbursement for diagnostic multi-analyte test offerings, such as:

- Gene expression classifiers for hematolymphoid neoplasms, such as the determination of activated B-cell like, or ABC, or germinal center B-cell like, or GCB, subtypes of diffuse large B-cell lymphomas
- Gene rearrangements in solid tumors and hematolymphoid neoplasms
- Mutations in solid tumors and hematolymphoid neoplasms

Payments for Tier 1 and Tier 2 Molecular Pathology Procedures and GSPs may be sought from both public and private payors. Claims for Medicare coverage are processed by private Medicare Administrative Contractors, or MACs, such as Novitas and Cahaba, and coverage for specific test codes are specified in Local Coverage Determinations, or LCDs, issued by individual MACs or National Coverage Determinations, or NCDs, which apply to all MACs. Private payors issue their own coverage determinations that are largely

reflective of the CMS LCDs and NCDs. HTG closely monitors trends in coverage through interactions with customers, industry associations such as the College of American Pathologists, or CAP, and the Association for Molecular Pathology, or AMP, and industry consultants; these trends are key considerations in our product development plans.

Our customers may use our products, subject to regulatory limitations, to offer testing services that provide an analysis of 5-50 genes as well as 51 or more genes. In October 2014, CMS released its preliminary determinations regarding the method for determining 2015 payment rates for new codes under the clinical laboratory fee schedule. CMS recommended that payment rates for GSPs be determined through a process known as gapfill rather than by crosswalking to allow CMS and its contractors to gather information about the manner in which the tests are performed and the resources necessary to provide them, so that ultimately CMS can set an appropriate payment rate for these tests. In the gapfill process, the local MACs determine the appropriate fee schedule amounts in the first year, and CMS calculates a national payment rate based on the median of these local fee schedule amounts in the second year. On September 27, 2015, gapfill pricing for CPTs 81445 and 81450 for the assessment of 5-50 genes in solid and liquid tumors, respectively, were set at $597 and $648, respectively, and remains the same as of December 31, 2016. CPT 81455 for the assessment of 51 or more genes in solid and liquid tumors has not yet been priced.

We believe that establishment of the aforementioned reimbursement codes specific to genomic sequencing procedures such as our clinical diagnostic tests currently in development is an important factor in expanding access to our products. In addition, coverage and reimbursement of our clinical diagnostic tests by government and private payors is essential to our commercial success. Accordingly, our strategy includes efforts to encourage third-party payors to establish coverage, coding and payment that will facilitate access to our tests as we seek FDA approval for these tests and expand our commercialization efforts in the United States. Our success in these efforts depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for tests using our technology. Failure by our customers who use our tests to obtain sufficient coverage and reimbursement from healthcare payors or adverse changes in government and private third-party payors' policies would have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments made under the Clinical Laboratory Fee Schedule, or CLFS, with amounts assigned to the procedure billing codes used to report the specific laboratory services. The CLFS sets the maximum amount payable under Medicare for each billing code. Payment under the CLFS has been limited from year-to-year by Congressional action such as imposition of national limitation amounts and freezes on the otherwise applicable annual consumer price index updates. In February 2012, the Middle-Class Tax Relief and Job Creation Act of 2012 was signed into law which, in part, reduced the potential future cost-based increases to the CLFS by 2%. The payment amounts under the CLFS are important not only for Medicare reimbursement, but also because although there is no uniform policy of coverage and reimbursement amongst third-party payors, other third-party payors are often guided by the Medicare CLFS in establishing reimbursement rates. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients. Because of the anticipated reduction in the CLFS payment amounts, certain third party payors may also reduce reimbursement amounts.

Beginning January 1, 2016, there will also be major changes to the payment formula under the CLFS. Under the Protecting Access to Medicare Act of 2014, which was signed to law in April 2014, 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.

***Outside the United States***

Our target markets outside of the United States are Europe and Asia/Pacific. Our diagnostic product menu plans for Europe and Asia/Pacific consist primarily of NGS-based test kits that will satisfy existing or emerging testing demand, and we expect to be competing based on testing efficiency, quality and price.

In Europe, coverage for molecular diagnostic testing is varied. Countries with statutory health insurance (e.g., Germany, France, The Netherlands) tend to be more progressive in technology adoption with favorable reimbursement for molecular diagnostic testing. In countries such as the United Kingdom with tax-based insurance, adoption and reimbursement for molecular diagnostic testing is not uniform and is influenced by local budgets.

In Asia/Pacific, our commercial strategy is to opportunistically partner with distributors in countries with sufficient demand for our products to justify the investment by both parties.

Our diagnostic product menu plans for Europe and Asia/Pacific consist primarily of NGS-based test kits that will satisfy existing or emerging testing demand, and we will be competing based on testing efficiency, quality and price. We plan to seek partners knowledgeable in local molecular diagnostic testing reimbursement practices and, working co-operatively with such partners, prepare, to the extent feasible, favorable reimbursement treatment for our diagnostic products in the applicable Asia/Pacific markets. Preferably, such favorable reimbursement decisions will coincide with or precede the launch of each applicable diagnostic product.

Failure by our ex-U.S. customers to obtain sufficient coverage and reimbursement for our diagnostic products from healthcare payors or adverse changes in government and private payors' policies would have a material adverse effect on our ex-U.S. growth prospects and our overall business, financial condition, and results of operations.

**Government Regulation – Medical Device Regulations**

***United States***

Our products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state, local and foreign authorities. Currently we are limited to marketing our products for research use only, which means that we cannot make any diagnostic or clinical claims. However, we intend to seek regulatory clearances or approvals in the United States and other jurisdictions to market certain assays for diagnostic purposes. The clinical diagnostics under development by HTG are classified as "medical devices" under the United States Food, Drug and Cosmetic Act, or FDCA. The FDA regulates, among other things, the research, development, testing, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of medical devices in the United States to assure the safety and effectiveness of such products for their intended use.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA submission can be expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

*Device Classification*

Under the FDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, guidelines and post market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to either:

- a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or
- another commercially available, similar device that was cleared through the 510(k) process.

To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence.

After a 510(k) notice is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite PMA application(s). In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

*The PMA Process*

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA process, or seek reclassification of the device through the *de novo* process. A manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally costlier and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical study data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction reasonable assurance of the safety and effectiveness of the device for its intended use.

In the United States, absent certain limited exceptions, human clinical studies intended to support medical device clearance or approval require an Investigational Device Exemption, or IDE, application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and Institutional Review Board approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical studies. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical studies for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical study sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical studies, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If the PMA application is determined to be sufficiently complete, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g. major deficiency letter) within a total of 360 days. Before approving or denying a

PMA, an FDA advisory panel may be convened to review the PMA and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. This advisory panel may also involve a public meeting if FDA determines public input is required. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical study data and clinical study sites, and a QSR inspection of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and clinical studies may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, which usually contains several conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional analytical studies or clinical studies are necessary, in which case approval of the PMA submission may be delayed for several months or years while the analytical studies and/or trials are conducted and data are submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modification to the manufacturing process, labeling, device specifications, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, the FDA may also require some form of post market studies or post market surveillance, whereby the applicant follows certain patient groups for several years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. FDA may also require post market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

*Post-Approval Requirements*

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include, but are not limited to:

- the registration and listing regulation, which requires manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution;
- the QSR, which requires manufacturers, including third party manufacturers, to follow elaborate design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations and unique device identification requirements;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- the FDA's general prohibition against promoting products for unapproved or "off-label" uses;
- the Medical Device Reporting, or MDR, regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur;

- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post approval study and post market surveillance requirements.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearances or approvals and criminal prosecution.

*Research Use Only*

A research use only, or RUO, product is one that is not intended for clinical diagnostic use and must be labeled "For Research Use Only. Not for use in diagnostic procedures." Products that are intended for research use only and are properly labeled as RUO are exempt from compliance with the FDA requirements discussed above, including the approval or clearance and QSR requirements. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities. The FDA may consider the totality of the circumstances surrounding distribution and use of an RUO product, including how the product is marketed, when determining its intended use.

***European Union***

The European Union, or EU, has also adopted requirements that affect our products. These requirements include establishing standards that address creating a certified quality system as well as several directives that address specific product areas. The most significant of these directives is the In Vitro Diagnostic Medical Device Directive, or IVDD, which includes:

- *Essential Requirements*. The IVDD specifies "essential requirements" that all medical devices must meet. The requirements are similar to those adopted by the FDA relating to quality systems and product labeling.
- *Conformity Assessment*. Unlike United States regulations, which require virtually all devices to undergo some level of premarket review by the FDA, the IVDD currently allows manufacturers to bring many devices to market using a process in which the manufacturer certifies that the device conforms to the essential requirements for that device. A small number of products must go through a more formal pre-market review process. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the EU and European Economic Area.
- *Vigilance*. The IVDD also specifies requirements for post market reporting similar to those adopted by the FDA.

***Other International***

Several other countries, including Australia, Canada, China and Japan, have adopted or are in the process of adopting standards for medical devices sold in those countries. Many of these standards are loosely patterned after those adopted by the European Union, but with elements unique to each country. Although there is a trend towards harmonization of quality system standards, regulations in each country may vary substantially, which can affect timelines of introduction. We routinely monitor these developments and address compliance with the various country requirements as new standards are adopted.

**Government Regulation – Fraud and Abuse and Other Healthcare Regulation**

We may be subject to various federal and state healthcare laws, including, but not limited to, anti-kickback laws. Penalties for violations of these healthcare laws include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs,

additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of operations.

*Federal Anti-Kickback Statute*

The Federal Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, or for the purchasing, leasing, ordering, or arranging for or recommending, any good, facility, service or item for which payment may be made in whole or in part under federal healthcare programs, such as the Medicare and Medicaid programs. The Federal Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term "remuneration" expressly includes kickbacks, bribes, or rebates and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value.

There are several statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Federal Anti-Kickback Statute. These statutory exceptions and safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they may not be prosecuted under the Federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more applicable statutory exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the Federal Anti-Kickback Statute was amended under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the intent to induce referrals need only be "one purpose" of the remuneration for violations of the Federal Anti-Kickback Statute. The ACA provides that the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act which is discussed below.

*Federal Civil False Claims Act*

The federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim to, or the knowing use of false statements to obtain payment from or approval by the Federal Government. Suits filed under the federal civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend a case brought under the federal civil False Claim Act. If an entity is determined to have violated the federal civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Many comparable state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the Federal Government.

*Federal Physician Self-Referral Prohibition*

We are also subject to the federal physician self-referral prohibitions, 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 the 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. Many states have their own self-referral laws as well, which in some cases apply to all third-party payors, not just Medicare and Medicaid.

*Federal Civil Monetary Penalties Statute*

The Federal Civil Monetary Penalties Statute, among other things, imposes fines against any person or entity who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

*Health Insurance Portability and Accountability Act of 1996*

The Federal Health Insurance Portability and Accountability Act, or HIPAA, created several additional federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations established uniform standards for certain covered entities, which are certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

*The Federal Physician Payments Sunshine Act*

The Federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics 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" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians, as defined above, and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1.0 million per year for "knowing failures."

*State Law Equivalents*

Many states have also adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers, as well as laws that restrict our marketing activities with health care professionals and entities, and require us to track and report payments and other transfers of value, including consulting fees, provided to healthcare professionals and entities. Some states mandate implementation of compliance programs to ensure compliance with these laws. We also are subject to foreign fraud and abuse laws, which vary by country. We may be subject to certain state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

*Healthcare Reform*

In March 2010, President Obama enacted the ACA, which is substantially changing healthcare financing and delivery by both governmental and private insurers, and is significantly impacting the medical device industry. The ACA's provisions of importance to our business include, but are not limited to, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, which became effective January 1, 2013. However, the Consolidated Appropriations Act of 2016, signed into law in December 2015, includes a two-year moratorium on the medical device excise tax 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.

Since its enactment in 2010, there have been judicial and Congressional challenges to certain aspects of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In January 2017, Congress also voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the ACA. Among other changes, the American Health Care Act would repeal the annual fee on certain brand prescription drugs and biologics imposed on manufacturers and importers, eliminate the 2.3% excise tax on medical devices, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage, and create refundable tax credits to assist individuals in buying health insurance. The American Health Care Act would also make significant changes to

Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements.

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.

The full impact of the ACA, its possible repeal, and any legislation passed to replace the ACE, 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.

***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

**Employees**

As of December 31, 2016, we had 82 full-time and 3 part-time employees, of which 10 are employed in administration, 13 in manufacturing and operations, 21 in research and development, five in regulatory and quality affairs, and 36 in Sales and marketing. We had three employees in Europe as of December 31, 2016, all others were in the United States. We believe that our success will depend, in part, on our ability to attract and retain qualified personnel. We have never experienced a work stoppage due to labor difficulties and believe that our relations with our employees are good. None of our U.S. employees are represented by labor unions. Collective bargaining is established by law in France and Germany. We and our European employees, who reside in France and Germany, have agreed to the terms of the applicable collective bargaining agreements.

Our ability to retain current talent and recruit new people into our Company is another critical factor in our performance. We have initiated multiple programs to promote our organizational culture and to identify the best possible new talent as the organization grows and new positions are made available. In 2016, we launched our five company value statements: embrace the mission, engage, build community, expect healthy tension and assume positive intent. We also adopted a cultural index tool which assesses new hire candidates for cultural fit and to encourage teamwork among existing employees.

**Corporate Information**

We were originally incorporated in Arizona in October 1997 as "High Throughput Genomics, Inc." In December 2000, we reincorporated in Delaware as "HTG, Inc." and in March 2011 we changed our name to "HTG Molecular Diagnostics, Inc." Our principal executive offices are located at 3430 E. Global Loop, Tucson, AZ 85706, and our telephone number is (877) 289-2615. Our corporate website address is www.htgmolecular.com. Information contained on or accessible through our website is not a part of this report, and the inclusion of our website address in this report is an inactive textual reference only.

This report contains references to our trademarks, including VERI/O, HTG Edge and HTG EdgeSeq, and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO in May 2015, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 in this Annual Report on Form 10-K as the "JOBS Act," and references to "emerging growth company" have the meaning associated with it in the JOBS Act.

**Item 1A. Risk Factors.**

*An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings, before deciding to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business.*

**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 $26.0 million and $21.4 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of $115.6 million. We expect that our losses will continue for the foreseeable future as we will be required to invest significant additional funds to support product development, including development of our next generation instrument platforms, development of our new HTG EdgeSeq panels, including our initial IVD assay, and the commercialization of our HTG EdgeSeq system and proprietary consumables. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities, 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 Annual Report on Form 10-K for the year ended December 31, 2016, includes disclosures regarding management's assessment of its ability to continue as a going concern and a report from our independent auditors that includes an explanatory paragraph regarding going concern, as our current liquidity position and 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 $115.6 million as of December 31, 2016. As of December 31, 2016, we had cash, cash equivalents and investments in short term available-for-sale securities of approximately $11.8 million, and had current liabilities of approximately $10.0 million plus an additional $14.0 million in long-term liabilities primarily attributable to our growth term loan and NuvoGen obligation. 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. 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.

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. In addition, if we default under

our term loan agreement, our lenders could foreclose on our assets, including substantially all of our cash which is held in accounts with our lenders.

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 December 31, 2016, we had $11.8 million outstanding under the term loan agreement, of which amount $6.4 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 $11.8 million. If we default under our term loan agreement, our lenders could foreclose on our assets, including substantially all of our cash, which is held in accounts with our lenders.

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. For fiscal years 2013 to 2017, NuvoGen agreed to accept annual fixed fees in the range of $425,000 to $800,000, paid in quarterly installments, and to defer the balance of any revenue-based payments. To date, we have paid NuvoGen approximately $6.3 million. We paid annual fixed fees of $575,000 and $725,000 for 2015 and 2016, respectively. As of December 31, 2016, we have not deferred any revenue-based payments. For 2017, our annual fixed fee payable to NuvoGen is $800,000, payable in quarterly installments. 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 2017 period by which 6% of revenue exceeds the $800,000 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 products to operate on or with NGS instrumentation could reduce demand for our products and result in a loss of customers.

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

Current medical device regulation in the United States and other jurisdictions requires manufacturers of IVD molecular profiling tests that use NGS detection, referred to as NGS IVD tests, to include in regulatory submissions, technical information about the NGS products that are required for performance of, but are not supplied with, the NGS IVD test. These regulatory agencies also require that the NGS instrumentation have “locked” software for the detection of the NGS IVD test results. Thus, to obtain regulatory approval for NGS IVD tests, manufacturers like us, currently must have arrangements with NGS product manufacturers to gain access to technical information and NGS instrument software. We currently have agreements with two NGS product manufacturers that grant us rights to develop, manufacture and sell up to six 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. 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 or DNA mutations, 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 have initiated development of a new version of our HTG EdgeSeq system that will target the lower-volume throughput lab market. This development 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) and single-cell analysis, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or effectively manage the transitions to new product offerings, our revenues and results of operations will be adversely impacted.

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

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

We face risks associated with launching new products and with undertaking to comply with regulatory requirements for certain of our products. If we encounter development or manufacturing challenges 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 EdgeSeq system and related proprietary panels, and future development and approval of diagnostic products, are key elements of our growth strategy that will require us to hire and retain additional sales and marketing, regulatory, manufacturing and quality assurance personnel. If we do not successfully forecast the timing and cost of the development of new panels and diagnostic products, the regulatory clearance or approval for product marketing of any future diagnostic products or the demand and commercialization costs of such products, or manage our anticipated expenses accordingly, our operating results will be harmed.

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

Our current customer base is primarily composed of biopharmaceutical companies, 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. In July 2016, we obtained CE marking in Europe for our HTG EdgeSeq system and HTG EdgeSeq DLBCL Cell of Origin Assay, which means that these products may be used for diagnostic purposes in Europe. Our success will depend, in part, upon our ability to increase our market penetration among our customer base 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 in the United States and other jurisdictions after obtaining the requisite regulatory clearances or approvals. We may not be able to successfully complete development of or commercialize any of our planned future tests and applications. To achieve these goals, we will need to conduct substantial research and development, conduct clinical validation studies, expend significant funds, expand and scale-up our research 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 our current and any future diagnostic products are effective in obtaining clinically relevant information that can inform treatment decisions, and that our HTG EdgeSeq systems and related panels can enable an equivalent or superior approach than other available technology. Furthermore, we expect that a combination of increasing the installed base of our HTG EdgeSeq systems and entering into additional service and custom assay development agreements with biopharmaceutical customers will drive increased demand for our relatively high margin panels. If we are not able to successfully increase our installed base and biopharmaceutical customer relationships, then sales of our panels, sample processing services to be performed by our VERI/O laboratory and our margins for these revenue items 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 considering the risks and difficulties we expect to encounter in the new, uncertain and rapidly evolving markets in which we compete. Because these markets are new and evolving, predicting their future growth and size is difficult. We expect that our visibility into future sales of our products, including volumes, prices and product mix between instruments, consumables and services, will continue to be limited and could result in unexpected fluctuations in our quarterly and annual operating results.

Numerous other factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, two customers accounted for 29% and 12% of our revenue for the year ended December 31, 2016 and two customers accounted for 38% and 7% for the year ended December 31, 2015. 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 or may depend on customer studies that have variable or indefinite timelines, and accordingly involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. 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 or service revenues on a period-to-period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems or service providers or to purchase systems or services other than ours.

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

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

Other arrangements might include a 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 December 31, 2016, approximately $186,000 of our inventory consisted of HTG EdgeSeq instruments held by customers who are evaluating and testing 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 HTG EdgeSeq system, 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 currently derived 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 and services will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- changes in government programs that provide funding to research institutions and companies;
- macroeconomic conditions and the political climate;
- changes in the regulatory environment;
- differences in budgetary cycles;
- market-driven pressures to consolidate operations and reduce costs; and
- market acceptance of relatively new technologies, such as ours.

We believe that any uncertainty regarding the availability of research funding may adversely affect our operating results and may adversely affect sales to customers or potential customers that rely on government funding. In addition, academic, governmental and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could result in spending reductions, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers to purchase our products. 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. Our VERI/O service laboratory was announced in June 2016. We currently market our products through our own sales force in the United States and Europe, and have distributors in parts of Europe, the Middle East and 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 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. Thus, before we can market or distribute our profiling panels, including our mRNA and miRNA panels, as IVD kits for use by clinical testing laboratories in the United States, we must first obtain pre-market clearance or pre-market approval from the FDA. Even if or when we apply for clearance or approval from the FDA for any of our products, the process can be lengthy and unpredictable. We are working collaboratively with multiple biopharmaceutical companies to clinically validate our HTG EdgeSeq DLBCL Cell of Origin Assay, which we believe can classify DLBCL as either ABC or GCB subtype 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 studies, we expect to complete the FDA submission for the HTG EdgeSeq ALK*Plus* Assay in 2017. We cannot provide any assurances that our clinical studies 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. We obtained the right to CE mark the HTG EdgeSeq DLBCL Cell of Origin Assay and the HTG EdgeSeq ALK*Plus* Assay for sale as an IVD in Europe, in July 2016 and March 2017, respectively. 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 studies of any product candidate that we intend to market as an IVD kit may not be successful. If we are unable to successfully complete non-clinical and clinical studies of our product candidates or experience significant delays in doing so, our business will be materially harmed.***

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

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

Our development costs will increase if we have material delays in any clinical study or if we need to perform more or larger clinical studies than planned. If the delays are significant, or if any of our products do not prove to be equivalent to a predicate device or safe or effective, as applicable, or do not receive required regulatory approvals, our financial results and the commercial prospects for our product candidates will be harmed. Furthermore, our inability to complete our clinical studies in a timely manner could jeopardize our ability to obtain regulatory approval.

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

We are currently focused on selling our 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 treatment for those diseases. We may experience reluctance, or refusal, on the part of physicians to order, and third-party payors to cover and provide adequate reimbursement for, our panels if the results of our research and clinical studies, and our sales and marketing activities relating to communication of these results, do not convey to physicians, third-party payors and patients that the HTG EdgeSeq systems and related profiling panels provide equivalent or better diagnostic information than other available technologies and methodologies. We believe our panels represent an emerging methodology in diagnosing disease states, and we may have to overcome resistance among physicians to adopting it for the marketing of our products to be successful. Even if we are able to obtain regulatory approval from the FDA, 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, and to perform sample processing and analysis services for biopharmaceutical customers through our VERI/O laboratory. 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 immuno-oncology, breast-related disorders, melanoma and other diseases. We intend to enter into additional similar agreements with life sciences companies, biopharmaceutical companies and other researchers for future diagnostic products. However, we cannot guarantee that we will enter into any additional agreements. In particular, our life sciences research or biopharmaceutical customers are not obligated to collaborate with us or license technology to us, and they may choose to develop diagnostic products themselves or collaborate with our competitors. Establishing 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 that we enter 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. 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. In addition, in some instances the cost to acquire samples can be prohibitively expensive. If we are not able to negotiate access to archived patient samples on a timely basis and on acceptable terms, or at all, or if our competitors or others secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

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

We face significant competition in the life sciences research and diagnostics markets. We currently compete with both established and early-stage life sciences research companies that design, manufacture and market instruments and consumables for gene expression analysis, liquid-based specimen analysis (e.g., plasma, blood and urine), single-cell analysis, PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well-established laboratory techniques such as microarrays or 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 Agilent Technologies, Inc., ArcherDx, Inc., BioRad Laboratories, Exiqon A/S, Fluidigm Corporation, Foundation Medicine, Inc., Genomic Health, Illumina, Inc., Abbott Molecular, Luminex Corporation, Affymetrix, Inc., NanoString Technologies, Inc., entities owned and controlled by QIAGEN, Roche Diagnostics, a division of the Roche Group of companies, and Thermo Fisher Scientific, Inc. In addition, there are several other market entrants in the process of developing novel technologies for the life sciences market, including companies such as 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 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 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 such suppliers. 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 our applicable product(s), which in turn would materially affect our ability to generate revenue. If any of these events occur, our business and operating results could be materially harmed.

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

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

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

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

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

We manufacture our consumable products and our HTG EdgeSeq system in our Tucson, Arizona facilities. In addition, our Tucson facilities are the center for order processing, receipt of critical components of our HTG EdgeSeq instrument and shipping products to customers. We do not have redundant facilities. Damage or the inability to utilize our Tucson facilities and the equipment we use to perform research 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 flooding, wind damage, power spikes and power outages, which may render it difficult or impossible for us to perform these critical functions for some period of time. The inability to manufacture consumables, 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 the year ended December 31, 2016, approximately 16% of our revenue was generated from sales to customers located outside of the United States, compared with 13% for the year ended December 31, 2015. 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 for sales of our products in several markets outside of the United States.***

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

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

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

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

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

***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.***

Existing 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, 2016, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $102.2 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 thus, 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, including new biopharmaceutical company customers. In particular, the commercialization of our HTG EdgeSeq system and related panels requires us to continue to establish and maintain 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, pollution, errors and omissions and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our HTG 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 natural or man-made hazards, such as fire, storm, flood, power loss, wind damage, telecommunications failures, physical or software break-ins, software viruses and similar events. These events could lead to the unauthorized access, disclosure and use of non-public information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. In addition, any sustained disruption in internet access provided by other companies could harm our business.

**Risks Related to Government Regulation and Diagnostic Product Reimbursement**

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

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

A significant change in the laws governing RUO products or how they are enforced may require us to change our business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only", 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, conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO status held by the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO tests until we are in compliance, which would reduce our revenues, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, the FDA's proposed implementation for a new framework for the regulation of Laboratory Developed Tests, or LDTs, may negatively impact the LDT market and thereby reduce demand for RUO products.

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

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

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

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

Sales of our diagnostic products outside the United States will be subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. In addition, the FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to commercialize our diagnostic products outside of the United States.

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

We do not have the ability to independently conduct the clinical studies or other studies that may be required to obtain FDA and other regulatory clearance or approval for our diagnostic products, including the HTG 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 created new CPT codes that could be used by our customers to report testing for certain large-scale multianalyte GSPs, including our diagnostic products, if approved. Effective January 1, 2015, these codes allow for uniform reporting of broad genomic testing panels using technology similar to ours. While these codes standardize reporting for these tests, coverage and payment rates for GSPs remain uncertain and we cannot guarantee that coverage and/or reimbursement for these tests will be provided in the amounts we expect, or at all. Initially, industry associations recommended that payment rates for GSPs be cross-walked to existing codes on the clinical laboratory fee schedule. On October 27, 2014, CMS issued preliminary determinations for 29 new molecular pathology codes, including the GSPs, of gapfill rather than crosswalking as recommended by the Association for Molecular Pathology. This means that local private MACs, such as Palmetto, Novidian, Novitas and Cahaba, were instructed to determine the appropriate fee schedule amounts in the first year, and CMS calculated a national payment rate based on the median of those local fee schedule amounts in the second year. This process may make it more difficult for our customers to obtain coverage and adequate reimbursement for testing services using our diagnostic products. We cannot assure that CMS and other third-party payors will establish reimbursement rates sufficient to cover the costs incurred by our customers in using our clinical diagnostic products, if approved. On September 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, rather, if one purpose of the remuneration is to induce referrals, the Federal Anti-Kickback Statute is violated;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral. Unlike the Federal Anti-Kickback Statute, the Stark Law is a strict liability statute, meaning that all of the requirements of a Stark Law exception must be met in order to be compliant with the law;
- federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other governmental third-party payors that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money to the Federal Government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the Federal Government, which may apply to entities that provide coding and billing advice to customers; the Federal Government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, maintenance, or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;
- 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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to, among other things: (i) comply with the regulations of the FDA, CMS, the Department of Health and Human Services Office of Inspector General, 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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

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

On April 1, 2014, the Protecting Access to Medicare Act of 2014, 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 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 Affordable Care Act makes changes that could significantly impact the biopharmaceutical and medical device industries and clinical laboratories. For example, the ACA imposes a multifactor productivity adjustment to the reimbursement rate paid under Medicare for certain clinical diagnostic laboratory tests, which may reduce payment rates. These or any future proposed or mandated reductions in payments may apply to some or all of the clinical laboratory tests that our diagnostics customers use our technology to deliver to Medicare beneficiaries, and may reduce demand for our diagnostic products.

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. Further, the ACA includes a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, which became effective January 1, 2013. However, the Consolidated Appropriations Act of 2016, signed into law in December 2015, includes a two-year moratorium on the medical device excise tax 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. However, the future of the ACA is uncertain. There have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in January 2017, Congress adopted a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the ACA. Among other changes, the American Health Care Act would repeal the annual fee on certain brand prescription drugs and biologics imposed on manufacturers and importers, eliminate the 2.3% excise tax on medical devices, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage, and create refundable tax credits to assist individuals in buying health insurance. The American Health Care Act would also make significant changes to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements. While it is uncertain when or if the provisions in the American Health Care Act will become law, or the extent to which any changes may impact our business, it is clear that concrete steps are being taken to repeal and replace certain aspects of the ACA.

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 DLBCL biomarker panels discovered using our nuclease-protection-based technology. We have exclusive or non-exclusive licenses to multiple U.S. and foreign patents and patent applications covering technologies that we may elect to utilize in developing diagnostic tests for use on our HTG 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 Stock Market, or NASDAQ. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. For the year ending December 31, 2016, we have performed 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 has required and will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts as we continue to make this assessment and ensure maintenance of proper internal controls on an ongoing basis.

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

Our common stock is currently listed on The NASDAQ Global Market under the symbol "HTGM." On August 15, 2016, we received notice from NASDAQ 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. On February 14, 2017, we received a letter (the "Delisting Notice") from NASDAQ stating that we did not regain compliance with the stockholders' equity requirement and that, as a result, our common stock would be removed from listing unless we requested on appeal to a NASDAQ Hearings Panel. On February 21, 2017, we appealed the delisting determination to a NASDAQ Hearings Panel (the "Panel"), pursuant to the procedures set forth in the NASDAQ Listing Rule 5800 series. The hearing request will stay any delisting action in connection with the Delisting Notice and allow the continued listing of our common stock on The NASDAQ Global Market until the Panel renders a decision. A hearing before the Panel has been scheduled for March 30, 2017. There can be no assurance that we will be successful in our appeal before the Panel or that we will otherwise be able to regain and maintain 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 NASDAQ, such as The NASDAQ Capital Market. If we are not afforded additional time by the Panel to regain compliance or if we are afforded additional time but are unable to timely regain compliance, our common stock will be delisted from trading on NASDAQ. The delisting of our common stock from trading on NASDAQ may have a material adverse effect on the market for, and liquidity and price of, our common stock and impair our ability to raise capital. Delisting from NASDAQ could also have other negative results, including, without limitation, the potential loss of confidence by customers and employees, the loss of institutional investor interest and fewer business development opportunities. If our common stock is delisted from trading on NASDAQ, trading of our common stock could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the OTC Markets or OTC Bulletin Board. In such event, it could become more difficult to dispose of or obtain accurate quotations for the price of our common stock, and there may also be a reduction in our coverage by security analysts and the news media, which may cause the price of our common stock to decline further.

***We expect that our stock price will fluctuate significantly.***

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

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

The stock market in general, and market prices for the securities of health technology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies.

These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

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

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

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

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

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

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 2014 Plan, our board of directors is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 Plan will automatically increase on January 1 of each year by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, our board of directors approved the granting of rights to eligible employees to purchase shares of our common stock pursuant to our 2014 Employee Stock Purchase Plan, or 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 March 17, 2017. 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 1B. Unresolved Staff Comments**

None.

**Item 2. Properties.**

Our 30,100 square feet of corporate facilities, including our administrative, laboratory and manufacturing spaces, are located in Tucson, Arizona. We occupy these facilities pursuant to two separate leases. The first lease concerns 17,500 square feet housing our administrative, manufacturing, and lab services facilities. The second lease concerns 12,600 square feet of space used for our research and development facilities. We amended these facilities leases in August 2015 to, among other things, align and extend the lease terms to expire in January 2021. In connection with the first lease term extension the landlord agreed to perform certain capital improvements to expand and improve the existing manufacturing facilities. In addition, we completed the expansion and improvement of our administrative and research and development facilities, resulting in the capitalization of additional leasehold improvements in 2016, which will be amortized over the remaining life of the lease. Base rent payable under the first lease is approximately $27,000 per month, and base rent payable under the second lease is approximately $16,000 per month, in each case for the remaining terms of the respective leases. The aggregate rents payable over the renewal term of the amended first lease represent an increase of $804,000, over the prior term rental rates for a five-year period. The amended second lease specified no rent increase over the prior term and the annual rent increases for the applicable space were eliminated.

Our landlord holds security deposits equal to a total of approximately $23,000. We believe that our existing facilities are adequate to meet our business requirements for the reasonably foreseeable future and that additional space will be available on commercially reasonable terms, if required.

**Item 3. 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 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

**Market Information**

Our common stock is traded on The NASDAQ Global Market under the symbol "HTGM." Trading of our common stock commenced on May 6, 2015 in connection with our initial public offering. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on The NASDAQ Global Market.

| Year ended December 31, 2015 | High | Low |
|---|---|---|
| Second quarter (beginning May 6, 2015) | 19.75 | 10.22 |
| Third quarter | 13.10 | 4.64 |
| Fourth quarter | 9.59 | 4.08 |

| Year ended December 31, 2016 | High | Low |
|---|---|---|
| First quarter | 4.68 | 2.03 |
| Second quarter | 4.17 | 2.07 |
| Third quarter | 3.09 | 2.13 |
| Fourth quarter | 4.45 | 1.82 |

On March 17, 2017, the last reported sale price of our common stock was $2.06 per share.

**Holders**

As of March 17, 2017, there were approximately 192 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

**Dividends**

We have never declared or paid any cash dividends on our common stock. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, our term loan agreement materially restricts, and future debt instruments we issue may materially restrict, our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after considering various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then-existing debt instruments and other factors the board of directors deems relevant.

**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 owning ten percent or more of any class of our equity securities or to any of our 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 $4.3 million were short-term available-for-sale securities, at fair value at December 31, 2016. As of December 31, 2016, we have expended approximately $44.6 million of the proceeds from our IPO on the following: (1) approximately $22.3 for sales and marketing and general and administrative expenses; (2) approximately $9.4 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 $6.1 million for the payment of principal and interest on our growth term loan; and (4) approximately $6.8 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 6. Selected Financial Data.**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis together with our financial statements and related notes included elsewhere in this Annual Report. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements due to various factors, including those set forth under the caption "Item 1A. Risk Factors."*

**Overview**

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

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

In 2014, we launched our HTG EdgeSeq technology, which generates a molecular profiling library for detection of RNA using NGS. Our HTG EdgeSeq assays are automated on either our HTG Edge or HTG EdgeSeq platform. Our HTG Edge platform is capable of running both our original, plate-based assays and our NGS-based HTG EdgeSeq assays. We continue to support a small number of customers interested in utilizing our plate-based assays (on a custom manufacturing basis); however, in 2016, based on market trends and customer feedback, we shifted our product focus fully to our NGS-based HTG EdgeSeq system. 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 improve the lab's workflow efficiency. Customers can also obtain the advantages of our proprietary technologies by engaging our VERI/O laboratory for pre-clinical and clinical research-related services. 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 $26.0 million and $21.4 million for the years ended December 31, 2016 and 2015, respectively, and had an accumulated deficit of $115.6 million as of December 31, 2016. As of December 31, 2016, we had available cash and cash equivalents totaling approximately $7.5 million and investments in highly liquid corporate and government debt securities totaling $4.3 million and had current liabilities of approximately $10.0 million plus an additional $14.0 million in long-term liabilities primarily attributable to our growth term loan and NuvoGen obligation. We believe that these factors raise substantial doubt about our ability to continue as a going concern. While we believe that our existing cash resources are sufficient to fund our operations until mid-way through the second quarter of 2017, we cannot provide assurances that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

We will need to raise additional capital in the near future to fund our continued operations. Additional capital may not be available 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 sufficient amounts or on terms acceptable to us, we may have to significantly reduce expenses, sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets. In addition, if we default under our term loan agreement, our lenders could foreclose on our assets, including substantially all of our cash which is held in accounts with our lenders.

**Factors Affecting our Performance**

Our business model has evolved and expanded since our IPO was completed in May 2015 primarily due to our success in the development of a biopharmaceutical customer base, entry into collaboration agreements with certain biopharmaceutical customers and changing customer demand from product sales to service offerings in our VERI/O laboratory. We believe the mix of product- and service-based revenues will continue to evolve over time as our product menu expands and, particularly, if we successfully develop one or more companion diagnostic products as a result of our work with biopharmaceutical customers. We believe that our future results of operations are dependent on several factors discussed below. While each of these areas present significant opportunities for us, they also pose significant risks and challenges that we must successfully address. See the section entitled "Risk Factors" for further discussion of these risks.

***Biopharmaceutical Biomarker and Companion Diagnostic Solutions***

Biopharmaceutical companies are working to improve the efficacy of their drugs by better targeting appropriate patients for specific therapies. Our products and services are being used by our biopharmaceutical company customers to identify molecular biomarkers that can help determine which patients will or will not respond to a drug candidate. These customers can obtain the benefits of our technology by purchasing our platform and assays for their internal use or by engaging us to perform certain services. Due to the increasing demand of our biopharmaceutical customers for services throughout 2016, we announced and branded our VERI/O service laboratory. Our VERI/O laboratory offers support for our biopharmaceutical customers in biomarker research and companion diagnostic development, and further expands our traditional service offerings, including molecular profiling of retrospective cohorts to support development of targeted and immuno-oncology therapies, building custom research-use-only panels to support early stage clinical programs and developing investigational-use companion diagnostic assays for use in Phase 3 registration trials. We believe our product and service solutions provide us with a growing number of opportunities to collaborate with biopharmaceutical companies in their drug development programs. Because our technology is being used for biomarker detection and, ultimately, patient registration in such programs, we believe we are well positioned to manufacture and commercialize high-value companion diagnostic assays required in the corresponding drug approvals. We track our pipeline of biopharmaceutical company programs as well as the number of such customers with whom we are working to measure our progress.

***Customer Adoption of HTG Technology***

Today we believe the primary measure of adoption for our technology is our companion diagnostic pipeline with biopharmaceutical companies discussed above. In the future, we expect increased sales of our instruments and consumables to our pharma customers or their contractors to support their internal research and drug development efforts and, as discussed below, to other customer segments as we add to our assay menu and, especially, as we launch high value diagnostic, including companion diagnostic, products. We currently market and sell on a limited and targeted basis our research use only applications to biopharmaceutical companies, academic translational research centers and in Europe, molecular testing labs.

Our ability to increase instrument and consumable revenue depends on several factors, including (i) adoption of our HTG EdgeSeq platforms by our customer base, including increasing market share for our proprietary panels for the research market; (ii) the efforts of our sales and marketing teams to demonstrate the utility of our products and technology; (iii) our ability to develop and market novel molecular profiling panels designed to meet customer needs, including unmet medical needs; (iv) our ability to demonstrate the benefits of our products to key opinion leaders so they will publish information supporting those benefits; (v) pricing and reimbursement; (vi) our ability to expand the addressable market of our HTG EdgeSeq platform through the development of new applications; (vii) our product capabilities compared with competition; and (viii) successful outcomes to our companion diagnostic collaborations. Given the length of our sales cycle, we have in the past experienced, and will likely in the future experience, fluctuations in our instrument and consumables sales on a period-to-period basis.

A key element of increasing adoption of our technology measured by instrument placements is our assay and panel "menu." Menu is defined as what assays are available for use on the instruments to satisfy customer needs. To sell additional instruments, grow our installed base and drive larger consumable annuities we must develop and commercialize new assays. Our arrangements with biopharmaceutical companies are expected to generate new menu items as well as our diagnostic development strategies in immuno-oncology and next generation pathology. As of December 31, 2016, we had an installed base of 47 HTG Edge and HTG EdgeSeq systems in various stages of use, including units that are under evaluation. We are focused on high quality instrument placements and consumable pull through as the primary indicators of commercial adoption and success in our business.

***Timing and effectiveness of research and development expenses***

Our spending on research and development may vary substantially from period to period due to the availability and cost of clinical samples, prioritization of research and development projects or timing of milestone payments under technology development

agreements. We have instituted a stage-gate based method of new product development managed by an innovation council which is led by our Chief Executive Officer. All programs are reviewed by time, quality and budgetary metrics at each phase of the project.

**Financial Operations Overview and Results of Operations**

***Comparison of the Years Ended December 31, 2016 and 2015***

| | Years Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2016 | 2015 | $ | % |
| Revenue: | | | | |
| Product | $ 2,759,942 | $ 3,532,028 | $ (772,086) | (22%) |
| Service | 2,372,788 | 183,758 | 2,189,030 | 1191% |
| Other | — | 325,789 | (325,789) | (100%) |
| Total revenue | 5,132,730 | 4,041,575 | 1,091,155 | 27% |
| Cost of revenue | 4,135,884 | 3,335,511 | 800,373 | 24% |
| Gross margin | 996,846 | 706,064 | 290,782 | 41% |
| Gross margin percentage | 19% | 17% | | |
| Operating expenses: | | | | |
| Selling, general and administrative | 17,427,777 | 14,994,410 | 2,433,367 | 16% |
| Research and development | 7,900,311 | 4,601,718 | 3,298,593 | 72% |
| Total operating expenses | 25,328,088 | 19,596,128 | 5,731,960 | 29% |
| Operating loss | (24,331,242) | (18,890,064) | (5,441,178) | 29% |
| Other income (expense) | | | | |
| Loss from change in stock warrant valuation | — | (239,683) | 239,683 | (100%) |
| Interest expense | (1,867,466) | (1,719,475) | (147,991) | 9% |
| Interest income | 112,413 | 85,859 | 26,554 | 31% |
| Loss on settlement of convertible debt | — | (705,217) | 705,217 | (100%) |
| Other | 56,863 | 80,978 | (24,115) | (30%) |
| Total other income (expense) | (1,698,190) | (2,497,538) | 799,348 | (32%) |
| Net loss before income taxes | (26,029,432) | (21,387,602) | (4,641,830) | 22% |
| Income taxes | 10,118 | 10,189 | (71) | (1%) |
| Net loss | $ (26,039,550) | $ (21,397,791) | $ (4,641,759) | 22% |

***Revenue***

We generate revenue from the sale of our HTG Edge and HTG EdgeSeq platforms and our consumables, which consist primarily of our proprietary molecular profiling panels and other assay components. Together, all such consumables may be referred to as assays, assay kits or kits. We also generate revenue through the sale of services related to our proprietary technology, such as sample processing, custom research-use-only assay development and, pursuant to collaboration agreements with our biopharmaceutical customers, development of IVD assays. Because of increased demand for sample processing by our biopharmaceutical customers, a trend that we expect to continue in future reporting periods, we announced and branded of our VERI/O laboratory service in the second quarter of 2016. Total revenue for the year ended December 31, 2016 increased by 27% to $5.1 million compared with total revenue of $4.0 million for the year ended December 31, 2015.

*Product revenue*

Product revenue includes revenue from the sale of our HTG Edge and HTG EdgeSeq instruments and related consumables, and was $2.8 million compared with $3.5 million for the year ended December 31, 2015, and was comprised of the following:

| | Years Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2016 | 2015 | $ | % |
| Instruments | $ 522,813 | $ 789,231 | $ (266,418) | (34%) |
| Consumables | 2,237,129 | 2,742,797 | (505,668) | (18%) |
| Total product sales | $ 2,759,942 | $ 3,532,028 | $ (772,086) | (22%) |

Revenue from the sale of our instruments for the year ended December 31, 2016 was $523,000 compared with $789,000 for the year ended December 31, 2015, and represented 10% and 20% of our total revenue for the years ended December 31, 2016 and 2015, respectively. The decrease in instrument revenue from 2016 to 2015 is primarily attributable to our focus on biopharmaceutical

customers whose preference has been to access our technology via services through our VERI/O laboratory. We expect our revenue mix to continue to contain a higher portion of biopharmaceutical service revenue in the near term until we enter the commercial clinical diagnostic market.

Revenue from the sale of consumables is derived from the sale of our research-use-only molecular profiling assays for use on our HTG EdgeSeq platform and from the sale of custom molecular profiling assays that we have developed for customers. Consumable revenue for the year ended December 31, 2016 was $2.2 million compared with $2.7 million for the year ended December 31, 2015, and represented 44% and 68% of our total revenue for the years ended December 31, 2016 and 2015, respectively. In addition to the increase in biopharmaceutical customer demand for services discussed above, we also experienced a significant reduction in consumable sales to a single customer from 2015 to 2016. The customer completed a large, retrospective sample analysis project in late 2015. While this customer continues to place orders for our miRNA panel, its 2016 consumable orders were significantly below their 2015 levels. We believe this is not an unusual occurrence in the research market where orders are project driven. Our total consumable sales to all other customers increased from 2015 to 2016.

*Service revenue*

Service revenue consists primarily of sample processing and molecular profiling of retrospective cohorts through our VERI/O laboratory, though it also includes the design of custom panels for biopharmaceutical customers and research services, resulting from research and development collaboration agreements with biopharmaceutical customers. Service revenue represented 46% and 5% of our total revenue for the years ended December 31, 2016 and 2015, respectively, and was comprised of the following:

| | Years Ended December 31, | | Change | |
|---|---|---|---|---|
| | 2016 | 2015 | $ | % |
| Custom assay development | $ 235,818 | $ 101,792 | $ 134,026 | 132% |
| Sample processing | 2,136,970 | 81,966 | 2,055,004 | 2507% |
| Total service revenue | $ 2,372,788 | $ 183,758 | $ 2,189,030 | 1191% |

The increase in service revenue for the period ended December 31, 2016 compared with 2015 reflects our success in continuing to grow our biopharmaceutical customer base and expand our ability to serve the needs of those customers through our VERI/O laboratory. We have been able to enter into new and expanding biopharmaceutical collaborations, partnering with biopharmaceutical company customers who have chosen the HTG EdgeSeq system for use in their drug development programs, and who primarily prefer to access our technology via services in our VERI/O laboratory. Because of existing development agreements with biopharmaceutical customers such as BMS and Merck KGaA, which were entered into in 2016, and continued efforts to expand our services to biopharmaceutical customers going forward, we expect our service revenue may continue to increase in both absolute dollars and as a percentage of total revenue in 2017.

***Cost of revenue and gross margin***

Cost of revenue includes the aggregate costs incurred in manufacturing, delivering, installing and servicing instruments and consumables, as well as the costs incurred for services performed for customers in our VERI/O laboratory. The components of our 2016 cost of revenue are material, subcomponent and service costs, manufacturing costs incurred internally (which include direct labor costs), and equipment and infrastructure expenses associated with the manufacturing and distribution of our products. Additionally, internal costs incurred in our VERI/O laboratory, including direct labor and consumables, are included in cost of revenue.

For the year ended December 31, 2015, cost of revenue also included manufacturing costs that were paid to third-party manufacturers who were responsible for the manufacturing of our instruments at that time. We completed capital improvements to our manufacturing facilities the first quarter of 2016, at which point we began manufacturing our instruments internally. Further, cost of revenue for the year ended December 31, 2015 included costs associated with our NIH grant program.

For the years ended December 31, 2016 and 2015, cost of revenue included significant fixed costs comprised primarily of manufacturing and service headcount, field service engineers and facilities. Due to the fixed nature of expenses associated with direct labor, equipment and infrastructure, we expect our cost of revenue as a percentage to decrease over time as we increase product and service revenue, further absorbing these fixed costs.

Cost of revenue increased by $800,000, or 24% for the year ended December 31, 2016 compared with the year ended December 31, 2015. Since 2014, we have directed most of our commercial and marketing efforts to our HTG EdgeSeq products that do not utilize our chemiluminescent reader technology. Based on market demand, we discontinued the active marketing of our original HTG Edge technology in December 2016; provided that we will continue to support HTG Edge consumable needs for a limited

number of customers on an as-requested custom manufacturing basis for some period of time. The increased cost of revenue in 2016 was primarily due to the write off of the remaining $360,000 value of our HTG Edge Reader inventory, the recording of a $133,000 excess inventory reserve for our original HTG Edge system and additional inventory write offs to cost of product revenue of approximately $167,000 relating to our HTG Edge and plate-based consumables technology during the year ended December 31, 2016.

Despite these non-cash charges, gross margin as a percentage of total revenue improved from 17% for the year ended December 31, 2015 to 19% for the year ended December 31, 2016. This percent improvement reflects an increase in product and service revenues, allowing us to further absorb our largely fixed manufacturing costs and an overall the reduction of manufacturing costs resulting from a change to internally manufactured instruments, which began early in 2016.

*Research and development expenses*

Research and development expenses represent costs to develop new proprietary panels and corresponding assays, to obtain FDA approval for our first U.S. IVD assay and to continue to develop and improve our HTG EdgeSeq platform. These expenses include payroll and related expenses, consulting expenses, laboratory supplies and equipment and amounts incurred under collaborative supply or development agreements. Research and development costs are expensed as incurred. Research and development expenses increased by $3.3 million, or 72%, for the year ended December 31, 2016 compared with the year ended December 31, 2015. We expect research and development costs to continue to increase in 2017 due to the ongoing development of our V2 chemistry and the possible resumption of our Project JANUS development efforts in the second half of 2017. In addition, we expect higher costs from collaboration projects under agreements with our biopharmaceutical customers and costs associated with the fourth and final submission for our first PMA.

*Selling, general and administrative expenses*

Selling, general and administrative expenses consist primarily of personnel costs for our sales and marketing, regulatory, legal, executive management and finance and accounting functions. The expenses also include third-party professional and consulting fees incurred by these functions, promotional expenses and facility and overhead costs for our administrative offices. Selling, general and administrative expenses increased by $2.4 million, or 16%, for the year ended December 31, 2016, compared with the year ended December 31, 2015. This year over year increase was primarily a result of operating as a public company for a full year, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and The NASDAQ Global Market, non-cash stock-based compensation expense, additional director and officer insurance costs, investor relations activities and other administrative and professional services. This increase also included higher sales and marketing costs related to a reorganization of our US-based commercial sales team, increased commercial sales activities in Europe, expansion of marketing efforts to accelerate market adoption of our products and commissions on overall increased revenue generated in 2016.

*Loss from change in stock warrant valuation*

Loss from the change in stock warrant valuation for the year ended December 31, 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, and 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 initial public offering. The increase in the fair value of our preferred stock warrants until their conversion to common stock warrants was primarily attributable to the proximity to and increased likelihood of completing an initial public offering. There was no loss from change in stock warrant valuation for the year ended December 31, 2016.

*Interest expense*

As of December 31, 2016, we had an obligation due to NuvoGen Research, LLC, or NuvoGen, in the amount of $8.6 million under an asset purchase agreement and an obligation due to a syndicate of two lending institutions of $11.8 million, net of discount and deferred financing costs under a growth term loan entered into in August 2014 and amended in August 2015 and June 2016.

Interest expense relating to borrowings under our term loan agreements and non-cash interest expense related to our obligation to NuvoGen increased by $148,000 for the year ended December 31, 2016 as compared with the year ended December 31, 2015. The year over year increase was primarily the result of interest, discount and final fee premium recognized in 2016 on the $5.0 million growth term loan borrowed in March 2016, partially offset by reduced interest on the original growth term loan and the NuvoGen obligation as principal payments were made on both liabilities in 2016.

*Loss on settlement of convertible debt*

With completion of our initial public offering in May 2015, our remaining convertible note debt discount and deferred financing costs relating to the convertible notes 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. There were no convertible notes outstanding during the year ended December 31, 2016.

***Cash Flows for the Years Ended December 31, 2016 and 2015***

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

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Net cash provided by (used in): | | |
| Operating activities | $ (22,234,208) | $ (19,243,273) |
| Investing activities | 24,422,214 | (32,184,889) |
| Financing activities | 2,025,670 | 51,108,753 |
| Increase (decrease) in cash and cash equivalents | $ 4,213,676 | $ (319,409) |

*Operating Activities*

Net cash used in operating activities for the year ended December 31, 2016 was $22.2 million and reflected (i) the net loss of $26.0 million, (ii) net non-cash items of $4.1 million, consisting primarily of depreciation and amortization of $1.5 million, amortization of the discount on the NuvoGen obligation of $0.2 million, amortization of the discount, deferred financing costs and final payment premium on the growth term loan of $0.6 million, provision for excess inventory of $0.7 million, stock-based compensation of $0.9 million and accrued interest on available-for-sale securities of $0.2 million and (iii) a net cash outflow from changes in balances of operating assets and liabilities of $0.3 million. The significant items comprising the changes in balances of operating assets and liabilities were an increase of $0.7 million in accounts receivable and an increase in deferred revenue of $0.3 million due primarily to up-front payments received from development agreements entered into in 2016.

Net cash used in operating activities for the year ended December 31, 2015 was $19.2 million and reflected (i) the net loss of $21.4 million, (ii) net non-cash items of $3.0 million, consisting primarily of amortization and write off at the time of our initial public offering of discount on convertible notes of $0.7 million, depreciation and amortization of $0.7 million, amortization of the discount on the NuvoGen obligation of $0.3 million, amortization of the discount and final payment premium on the growth term loan of $0.3 million, provision for excess inventory of $0.2 million, stock-based compensation of $0.4 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 $0.9 million. The significant items comprising the changes in balances of operating assets and liabilities were an increase of $0.7 million in inventory and an increase in prepaid and other of $0.3 million.

*Investing Activities*

Net cash provided by investing activities of $24.4 million for the year ended December 31, 2016 consisted primarily of the purchase of $3.4 million and sales, redemptions and maturities of $29.8 million of available-for-sale securities originally acquired with proceeds from our initial public offering. This was partially offset by investments in leasehold improvements and laboratory equipment of $1.9 million with capital improvements made to our manufacturing and research and development facilities during the year.

Net cash used in investing activities of $32.2 million for the year ended December 31, 2015 consisted primarily of the purchase of $38.3 million and sales, redemptions and maturities of $7.5 million of available-for-sale securities originally acquired with proceeds from our initial public offering. Additional investment was made in the purchase of $1.3 million of laboratory and office equipment during the year.

*Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2016 of $2.0 million included $5.0 million from the draw of our growth term loan B availability in March 2016 to fund ongoing business operations and $2.0 million in proceeds from an investment in our common stock by a strategic investor, partially offset by $4.4 million in payments on our growth term loan balance, as principal payments resumed in April 2016, and $0.6 million in quarterly payments made on our NuvoGen obligation.

Net cash provided by financing activities for the year ended December 31, 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 instrument and consumables sales, services revenue and other income. Through December 31, 2016, we had received net proceeds of $52.9 million from 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 loans (net of $0.4 million original issue discount), $4.5 million from convertible note issuances, $36.4 million from product and service revenue and $2.0 million from an investment in our common stock by a private investor. As of December 31, 2016, we had cash, cash equivalents and short-term available-for-sale investments totaling $11.8 million. Our liabilities include $20.6 million of debt outstanding on our growth term loan payable, NuvoGen obligation and capital lease obligations.

On May 11, 2015, we completed the initial closing of our initial public offering, where we sold 3,570,000 shares of our common stock at a price of $14.00 per share, which excluded the underwriters' exercise of their over-allotment option, available for thirty days after May 5, 2015. We received additional net proceeds of approximately $1.3 million with the sale of 90,076 additional shares of our common stock at $14.00 per share pursuant to the partial exercise by our underwriters of their over-allotment option. We raised approximately $45.4 million in net proceeds from our initial public offering, after deducting underwriting discounts and commissions of $3.6 million and offering expenses of $2.3 million. These costs have been recorded as a reduction of the proceeds received in arriving at the amount recorded in additional paid-in capital. In connection with the closing of the initial public offering, all outstanding shares of our preferred stock were converted into 2,134,192 shares of common stock.

In August 2014, we entered into an asset-secured growth capital term loan with Oxford Finance, LLC and Silicon Valley Bank, at which time we borrowed the first tranche of the term loan in the amount of $11.0 million. The loan accrues interest annually at the rate of 8.5% and matures on September 1, 2018, and pursuant to our August 2015 amendment, was payable in monthly interest-only payments through March 31, 2016, followed by equal monthly payments of principal and interest amortized over the remaining term of the loan will be due. In March 2016, we drew on the remaining $5.0 million availability under our Growth Term Loan agreement. This additional principal accrues interest at a rate of 8.75% and is being repaid evenly over the course of 30 months beginning April 1, 2016.

***Funding Requirements***

We have had recurring operating losses and negative cash flows from operations since inception, and we had an accumulated deficit of approximately $115.6 million as of December 31, 2016. As of December 31, 2016, we had available cash, cash equivalents and investments in short term available-for-sale securities of approximately $11.8 million, and had current liabilities of approximately $10.0 million plus an additional $14.0 million in long-term liabilities primarily attributable to our growth term loan and NuvoGen obligation. 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, seek other protection from creditors, or

liquidate all of our assets. In addition, if we default under our term loan agreement, our lenders could foreclose on our assets, including substantially all of our cash which is held in accounts with our lenders.

**Contractual Obligations**

The following table summarizes our contractual obligation as of December 31, 2016:

| | Payments due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less Than 1 Year | 1 - 3 Years | 3 - 5 Years | More Than 5 Years |
| Debt obligations (1) | $ 21,942,411 | $ 7,933,524 | $ 7,310,144 | $ 1,200,000 | $ 5,498,743 |
| Operating lease obligations (2) | 2,153,439 | 524,861 | 1,585,439 | 43,139 | — |
| Capital lease obligations (3) | 164,125 | 116,850 | 47,275 | — | — |
| Total contractual obligations | $ 24,259,975 | $ 8,575,235 | $ 8,942,858 | $ 1,243,139 | $ 5,498,743 |

(1) Our debt obligations include amounts due to NuvoGen under an asset purchase agreement and, beginning in 2018, includes 2.5% interest on the then-remaining obligation. Through 2017, we owe a specified fixed fee under the NuvoGen agreement. Beginning in 2018, we are obligated to pay the greater of $400,000 or 6% of sales plus amounts, if any, deferred in the 2017 period by which 6% of revenue exceeds the applicable fixed fee plus 5% interest on any such deferred amounts until the obligation is paid in full. Our debt obligations further include our contractual obligations pursuant to our outstanding $16.0 million term loan under our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank entered into in 2014 and amended in 2015 and 2016. The table above includes contractual interest payments and a final premium fee relating to this loan. Refer to Note 8 of our audited financial statements in Item 8 for payments due under the term loan.

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

(3) Our capital lease obligations consist of an equipment financing arrangement with a vendor and several computer equipment leases which were entered into on various dates between December 2012 and December 2016.

**Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

**Recent Accounting Pronouncements**

For a summary of recent accounting pronouncements applicable to our financial statements see “Note 2. Basis of Presentation and Summary of Significant Accounting Policies” in Part II, Item 8, Notes to Financial Statements, which is incorporated herein by reference.

**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 U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the 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, fair value measurements, the resolution of uncertain tax positions, income tax valuation allowances, recovery of long-lived assets and provisions for doubtful accounts, inventory obsolescence and inventory valuation. Actual results could differ from these estimates and such differences could affect the results of operations in future periods.

***Revenue Recognition***

*Product revenue*

We recognize revenue from the sale of instruments, consumables, sample processing, custom assay development and collaboration service when the following four basic criteria are met: (1) a contract has been entered into with a customer or persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed or determinable, and (4) collectability is reasonably assured.

*Sale of instruments and consumables*

Instrument product revenue is generally recognized upon installation and calibration of the instrument by our field service engineers, unless the customer has specified any other acceptance criteria. The sale of instruments and related installation and calibration are considered to be one unit of accounting, as instruments are required to be professionally installed and calibrated before use. Installation generally occurs within a month of shipment.

Consumables are considered to be separate units of accounting as they are sold separately. Consumables revenue is recognized upon transfer of ownership. Our standard terms and conditions provide that no right of return exists for instruments or consumables unless replacement is necessary due to delivery of defective or damaged products.

When a contract involves multiple elements, the items included in the arrangement, referred to as deliverables, are evaluated to determine whether they represent separate units of accounting in accordance with ASC 605-25, *Revenue Recognition – Multiple-Element Arrangements,* or ASC 605-25. We perform this evaluation at the inception of an arrangement and as each item is delivered in the arrangement. Generally, we account for a deliverable (or a group of deliverables) separately if the delivered item has stand-alone value to the customer and delivery or performance of the undelivered item or service is probable and substantially in our control. When multiple elements can be separated into separate units of accounting, arrangement consideration is allocated at the inception of the arrangement, based on each deliverables' relative selling price. All revenue from contracts determined not to have separate units of accounting is recognized based on consideration of the most substantive delivery factor of all the elements in the contract.

We provide instruments to customers under reagent rental agreements. Under these agreements, we install instruments in the customer's facility without a fee and the customer agrees to purchase consumable products at a stated price over the term of the agreement. 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 entered into in 2015, and will continue to do so on future agreements. Terms range from several months to multiple years and may automatically renew in several month or multiple year increments unless either party notifies the other in advance that the agreement will not renew. This represents a multiple element arrangement and because all consideration under the reagent rental agreement is contingent on the sale of consumables, no consideration is allocated to the instrument and no revenue is recognized upon installation of the instrument. 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.

We retain title to the instrument in reagent rental agreements and such title is transferred to the customer at no additional charge at the conclusion of the initial arrangement. Because the pattern of revenue from the arrangement cannot be reasonably estimated, the cost of the instrument is amortized on a straight-line basis over the term of the arrangement, unless there is no minimum consumable product purchase in which case the instrument would be expensed as cost of revenue. Cost to maintain the equipment while title remains with us is charged to cost of sales as incurred.

*Service revenue*

We enter into custom assay development agreements and collaborative agreements that may generate up-front fees and subsequent payments which might be earned upon completion of development-related services. We are able to estimate the total cost of services under these arrangements and recognize revenue using a proportional performance revenue recognition model, under which revenue is recognized as performance occurs based on the delivery of the relative outputs under the respective agreement. Costs incurred to date compared to total expected costs is used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangements. Revenue recognized at any point in time is limited to cash that we have received and amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. From period to period, collaboration and custom assay development revenue can fluctuate substantially based on the achievement of development-related milestones.

*Sample Processing Services*

Our VERI/O laboratory also provides sample processing services for our customers, whereby the customer provides samples to be processed using our HTG EdgeSeq technology. Customers are charged a per sample fee for sample processing services which is recognized as revenue upon delivery of a data file to the customer showing the results of testing, and completing delivery of the agreed upon service.

*Multiple-Element Arrangements*

We account for contracts which combine one or more services, or services with sales of products or consumables as multiple element arrangements under ASC 605-25, as described under sale of instruments and consumables above. Anticipated losses, if any, on contracts are charged to earnings as soon as they are identified. Anticipated losses cover all costs allocable to contracts. Revenue

arising from claims or change orders is recorded either as income or as an offset against a potential loss only when the amount of the claim can be estimated and its realization is probable.

***Fair Value Measurements***

We establish the fair value of all of our financial assets and liabilities, which are recognized and disclosed at fair value in the financial statements, using the price that would be received to sell an asset or paid to transfer a financial liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy is used to measure fair value. The three levels of the fair value hierarchy are as follows:

Level 1 – Quoted prices in active markets for identical assets and liabilities.

Level 2 – Pricing inputs are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 – Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable and include situations where there is little, if any, market activity for the investment.

Our portfolio of securities comprises U.S. Treasuries, U.S. government sponsored agency obligations and high credit quality corporate debt securities classified as available-for-sale securities.

As discussed in Note 4, Fair Value, in Part II, Item 8 of this Form 10-K, a majority of our security holdings have been classified as Level 2. These securities have been initially valued at the transaction price and subsequently valued utilizing a third-party service provider who assesses the fair value using inputs other than quoted prices that are observable either directly or indirectly, such as yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instrument or debt, broker and dealer quotes, as well as other relevant economic measures. We perform certain procedures to corroborate the fair value of these holdings, and, in the process, we apply judgment and estimates that if changed, could significantly affect our statement of financial position.

***Inventory Valuation***

Inventory consists of raw materials and finished goods which are stated at the lower of cost (first-in, first-out) or market. We reserve or write down inventory for estimated obsolescence, inventory in excess of reasonably expected near term sales or unmarketable inventory, in an amount equal to the difference between the cost of inventory and the estimated market value, based upon assumption about future demand and market conditions. If actual market conditions are less favorable than those projected, additional inventory adjustments may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not reversed subsequently to income, even if circumstances later suggest that increased carrying amounts are recoverable.

***Stock-Based Compensation***

We recognize compensation costs related to stock-based payments to employees, including grants of stock options and restricted stock units, or RSUs, and our employee stock purchase plan, based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. The fair value of RSUs is based on the quoted market price of our common stock on the date of grant. The fair value of ESPP rights and stock options granted pursuant to our equity incentive plans is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value using the Black-Scholes option pricing model is affected by the fair value of our common stock and several assumptions, including volatility, expected term, risk-free interest rate and dividend yield. Generally, these assumptions are based on historical information and judgment is required to determine if historical trends may be indicators of future outcomes. These estimates involve inherent uncertainties. Changes to the assumptions that we have used in the Black-Sholes option pricing model and the forfeiture rate could significantly impact the compensation expense that has been recognized in our statements of operations. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different.

***Income Taxes***

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts and tax base of assets and liabilities using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established against net deferred tax assets for the uncertainty it presents of our ability to use the net deferred tax assets, in this case, primarily carryforwards of net operating tax losses and research and development tax credits. In assessing the realizability of net deferred tax assets we have assessed the likelihood that net deferred tax assets will be recovered from future taxable income, and to

the extent that recovery is not "more likely than not" or there is insufficient operating history, a valuation allowance is established. We record the valuation allowance in the period we determine that it is not more likely than not that net deferred tax assets will be realized. For the years ended December 31, 2016 and 2015, we have provided a full valuation allowance for all net deferred tax assets due to their current realization being considered remote in the near term. Uncertain tax positions taken or expected to be taken in a tax return are accounted for using the more likely than not threshold for financial statement recognition and measurement.

***Emerging Growth Company Status***

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or 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 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $11.8 million at December 31, 2016, which consist of bank deposits and 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 comprising 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 had a material impact on our results of operations during the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to potentially greater fluctuations due to changes in foreign currency exchange rates, which could increasingly affect our operating results. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

**Item 8. Financial Statements and Supplementary Data.**

**INDEX TO FINANCIAL STATEMENTS**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of HTG Molecular Diagnostics, Inc.
Tucson, Arizona

We have audited the accompanying balance sheets of HTG Molecular Diagnostics, Inc. (the "Company") as of December 31, 2016 and 2015 and the related statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the financial statements, the Company has had recurring operating losses and negative cash flows from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Phoenix, Arizona
March 23, 2017

**HTG Molecular Diagnostics, Inc.**
**Balance Sheets**

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 7,507,659 | $ 3,293,983 |
| Short-term investments available-for-sale, at fair value | 4,304,901 | 28,201,507 |
| Accounts receivable | 1,377,441 | 716,246 |
| Inventory, net of allowance of $270,307 at December 31, 2016 and $284,319 at December 31, 2015 | 1,511,053 | 2,201,301 |
| Prepaid expenses and other | 433,328 | 445,217 |
| Total current assets | 15,134,382 | 34,858,254 |
| Long-term investments available-for-sale, at fair value | — | 2,603,901 |
| Deferred offering costs | 49,630 | — |
| Property and equipment, net | 3,270,197 | 1,932,213 |
| Total assets | $ 18,454,209 | $ 39,394,368 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 761,663 | $ 724,805 |
| Accrued liabilities | 1,670,286 | 1,915,268 |
| Deferred revenue, current portion | 335,659 | 47,476 |
| NuvoGen obligation | 604,751 | 543,750 |
| Term loan | 6,389,782 | 3,059,068 |
| Other current liabilities | 258,850 | 29,243 |
| Total current liabilities | 10,020,991 | 6,319,610 |
| Term loan payable - non-current, net of discount and debt issuance costs | 5,389,137 | 7,737,586 |
| NuvoGen obligation - non-current, net of discount | 8,017,356 | 8,415,122 |
| Other | 619,587 | 28,652 |
| Total liabilities | 24,047,071 | 22,500,970 |
| Commitments and Contingencies | | |
| Stockholders' equity (deficit): | | |
| Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2016, and December 31, 2015, 7,939,967 and 7,938,571 shares issued and outstanding, respectively, at December 31, 2016, 6,845,638 and 6,844,242 shares issued and outstanding, respectively, at December 31, 2015 | 7,938 | 6,844 |
| Additional paid-in-capital | 110,081,334 | 106,569,405 |
| Treasury stock – 1,396 shares, at cost | (75,000) | (75,000) |
| Accumulated other comprehensive loss | (1,090) | (41,357) |
| Accumulated deficit | (115,606,044) | (89,566,494) |
| Total stockholders' equity (deficit) | (5,592,862) | 16,893,398 |
| Total liabilities and stockholders' equity (deficit) | $ 18,454,209 | $ 39,394,368 |

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

**HTG Molecular Diagnostics, Inc.**
**Statements of Operations**

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| **Revenue:** | | |
| Product | $ 2,759,942 | $ 3,532,028 |
| Service | 2,372,788 | 183,758 |
| Other | — | 325,789 |
| Total revenue | 5,132,730 | 4,041,575 |
| Cost of revenue | 4,135,884 | 3,335,511 |
| Gross margin | 996,846 | 706,064 |
| | | |
| **Operating expenses:** | | |
| Selling, general and administrative | 17,427,777 | 14,994,410 |
| Research and development | 7,900,311 | 4,601,718 |
| Total operating expenses | 25,328,088 | 19,596,128 |
| Operating loss | (24,331,242) | (18,890,064) |
| | | |
| Other income (expense): | | |
| Loss from change in stock warrant valuation | — | (239,683) |
| Interest expense | (1,867,466) | (1,719,475) |
| Interest income | 112,413 | 85,859 |
| Loss on settlement of convertible debt | — | (705,217) |
| Other | 56,863 | 80,978 |
| Total other income (expense) | (1,698,190) | (2,497,538) |
| Net loss before income taxes | (26,029,432) | (21,387,602) |
| Income taxes | 10,118 | 10,189 |
| Net loss | (26,039,550) | (21,397,791) |
| 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 | $ (26,039,550) | $ (22,726,385) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (3.66) | $ (5.03) |
| Shares used in computing net loss per share attributable to common stockholders, basic and diluted | 7,113,075 | 4,518,499 |

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

**HTG Molecular Diagnostics, Inc.**
**Statements of Comprehensive Loss**

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Net loss | $ (26,039,550) | $ (21,397,791) |
| Other comprehensive income (loss), net of tax effect: | | |
| Unrealized gain (loss) on short and long-term investments | 40,267 | (41,357) |
| Comprehensive loss | (25,999,283) | (21,439,148) |
| 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 | $ (25,999,283) | $ (22,767,742) |

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

**HTG Molecular Diagnostics, Inc.**
**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**

| | Redeemable Convertible Preferred Stock | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Series A | | Series B | | Series C-1 | | Series C-2 | | Series D | | Series E | |
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount |
| Balance at January 1, 2015 | 1,292,084 | $ 1,402,687 | 6,789,712 | $ 2,099,310 | 13,242,612 | $ 4,567,525 | 9,948,331 | $ 2,223,506 | 139,529,173 | $ 37,174,666 | 45,938,041 | $ 8,454,899 |
| Exercise of Series D and Series E warrants | — | — | — | — | — | — | — | — | 723,505 | 93,550 | 51,681 | 11,312 |
| Exercise of stock options | — | — | — | — | — | — | — | — | — | — | — | — |
| Stock issued under stock purchase plan | — | — | — | — | — | — | — | — | — | — | — | — |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | — | — | — |
| Accretion of redeemable convertible preferred stock issuance costs | — | 320 | — | 839 | — | 1,538 | — | 2,113 | — | 18,109 | — | 12,127 |
| Accretion of Series E warrant discount | — | — | — | — | — | — | — | — | — | — | — | 127,616 |
| Accretion of Series D and E redeemable convertible preferred stock dividends | — | — | — | — | — | — | — | — | — | 876,955 | — | 288,977 |
| Conversion of outstanding principal and accrued interest on convertible notes by issuance of common stock | — | — | — | — | — | — | — | — | — | — | — | — |
| Conversion of warrants from warrants for preferred stock to warrants for common stock | — | — | — | — | — | — | — | — | — | — | — | — |
| Conversion of preferred stock into common stock at initial public offering | (1,292,084) | (1,403,007) | (6,789,712) | (2,100,149) | (13,242,612) | (4,569,063) | (9,948,331) | (2,225,619) | (140,252,678) | (38,163,280) | (45,989,722) | (8,894,931) |
| Issuance of common stock from initial public offering net of issuance costs of $5.9 million | — | — | — | — | — | — | — | — | — | — | — | — |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — |
| Other comprehensive loss | — | — | — | — | — | — | — | — | — | — | — | — |
| Balance at December 31, 2015 | — | $ — | — | $ — | — | $ — | — | $ — | — | $ — | — | $ — |
| Stock issued for payment of 2015 annual bonus | | | | | | | | | | | | |
| Exercise of stock options | — | — | — | — | — | — | — | — | — | — | — | — |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | — | — | — |
| Vesting of restricted stock units | — | — | — | — | — | — | — | — | — | — | — | — |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Employee stock purchase plan purchases | — | — | — | — | — | — | — | — | — | — | — | — | — |
| Stock issued for private investment | — | — | — | — | — | — | — | — | — | — | — | — | — |
| Growth Term Loan B warrant discount | — | — | — | — | — | — | — | — | — | — | — | — | — |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — | — |
| Other comprehensive income | — | — | — | — | — | — | — | — | — | — | — | — | — |
| Balance at December 31, 2016 | — | $ — | — | $ — | — | $ — | — | $ — | — | — | $ — | — | $ — |

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

**HTG Molecular Diagnostics, Inc.**
**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (Continued)**

| | Common Stock | | Additional Paid-In | Treasury | Accumulated Other Comprehensive | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Stock | Loss | Deficit | Equity (Deficit) |
| Balance at January 1, 2015 | 332,607 | $ 333 | (1,426,556) | $ (75,000) | $ — | $ (68,168,703) | $ (69,669,926) |
| Exercise of Series D and Series E warrants | — | — | — | — | — | — | — |
| Exercise of stock options | 13,960 | 14 | 34,867 | — | — | — | 34,881 |
| Stock issued under stock purchase plan | 4,184 | 4 | 19,996 | — | — | — | 20,000 |
| Stock-based compensation expense | — | — | 405,426 | — | — | — | 405,426 |
| Accretion of redeemable convertible preferred stock issuance costs | — | — | (35,046) | — | — | — | (35,046) |
| Accretion of Series E warrant discount | — | — | (127,616) | — | — | — | (127,616) |
| Accretion of Series D and E redeemable convertible preferred stock dividends | — | — | (1,165,932) | — | — | — | (1,165,932) |
| Conversion of outstanding principal and accrued interest on convertible notes by issuance of common stock | 324,591 | 324 | 4,544,060 | — | — | — | 4,544,384 |
| Conversion of warrants from warrants for preferred stock to warrants for common stock | — | — | 1,616,140 | — | — | — | 1,616,140 |
| Conversion of preferred stock into common stock at initial public offering | 2,508,824 | 2,509 | 57,353,540 | — | — | — | 57,356,049 |
| Issuance of common stock from initial public offering net of issuance costs of $5.9 million | 3,660,076 | 3,660 | 45,350,526 | — | — | — | 45,354,186 |
| Net loss | — | — | — | — | — | (21,397,791) | (21,397,791) |
| Other comprehensive loss | — | — | — | — | (41,357) | — | (41,357) |
| Balance at December 31, 2015 | 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 | 11,093 | 11 | 23,840 | — | — | — | 23,851 |
| Stock-based compensation expense | — | — | 903,547 | — | — | — | 903,547 |
| Vesting of restricted stock units | 36,762 | 37 | — | — | — | — | 37 |
| Employee stock purchase plan | 79,962 | 80 | 273,138 | — | — | — | 273,218 |
| Stock issued for private investment | 833,333 | 833 | 1,824,167 | — | — | — | 1,825,000 |
| Growth Term Loan B warrant discount | — | — | 122,460 | — | — | — | 122,460 |
| Net loss | — | — | — | — | — | (26,039,550) | (26,039,550) |
| Other comprehensive income | — | — | — | — | 40,267 | — | 40,267 |
| Balance at December 31, 2016 | 7,938,571 | $ 7,938 | $ 110,081,334 | $ (75,000) | $ (1,090) | $ (115,606,044) | $ (5,592,862) |

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

**HTG Molecular Diagnostics, Inc.**
**Statements of Cash Flows**

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| **Operating activities** | | |
| Net loss | $ (26,039,550) | $ (21,397,791) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,473,778 | 662,562 |
| Accretion of discount on NuvoGen obligation | 206,985 | 281,013 |
| Bad debt expense, net of recoveries | — | 44,854 |
| Provision for excess inventory | 723,466 | 230,754 |
| Amortization of Growth Term Loan discount and issuance costs | 551,121 | 352,415 |
| Loss on settlement of convertible notes | — | 705,217 |
| Amortization of convertible note discount and issuance costs | — | 112,134 |
| Stock-based compensation expense | 903,584 | 405,426 |
| Employee stock purchase plan expense | 98,544 | — |
| Change in redeemable convertible preferred stock warrant liability | — | 239,683 |
| Accretion of incentive from landlord | (130,167) | — |
| Amortization of premiums and discounts and accrued interest on available-for-sale securities investments | 172,045 | — |
| Loss on disposal of assets | 98,685 | 12,125 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (661,195) | 40,025 |
| Inventory | (33,218) | (746,241) |
| Prepaid expenses and other | 11,889 | (334,536) |
| Accounts payable | 10,073 | (312,275) |
| Accrued liabilities | 119,928 | 455,620 |
| Deferred revenue | 259,824 | 6,228 |
| Other long term liabilities | — | (486) |
| Net cash used in operating activities | (22,234,208) | (19,243,273) |
| **Investing activities** | | |
| Purchase of property and equipment | (1,946,515) | (1,338,124) |
| Sales, redemptions and maturities of available-for-sale securities | 29,750,000 | 7,500,000 |
| Purchase of available-for-sale securities | (3,381,271) | (38,346,765) |
| Net cash provided by (used in) investing activities | 24,422,214 | (32,184,889) |
| **Financing activities** | | |
| Proceeds from initial public offering | — | 47,654,190 |
| Deferred offering costs | (49,630) | (1,002,930) |
| Proceeds from private investors | 2,000,000 | — |
| Proceeds from Growth Term Loan | 5,000,000 | — |
| Payments on Growth Term Loan | (4,446,396) | — |
| Proceeds from convertible notes | — | 4,500,000 |
| Deferred financing costs | — | (75,523) |
| Payments on capital leases | (133,079) | (29,242) |
| Proceeds from exercise of stock options | 23,851 | 34,881 |
| Proceeds from exercise of Series E warrants | — | 8,948 |
| Proceeds from issuance of convertible note warrants | — | 1,354 |
| Proceeds from stock purchased under stock purchase plans | — | 20,000 |
| Proceeds from stock purchased under the employee stock purchase plan | 174,674 | — |
| Payments on NuvoGen obligation | (543,750) | — |
| Settlement of fractional common shares | — | (2,925) |
| Net cash provided by financing activities | 2,025,670 | 51,108,753 |
| Increase (decrease) in cash and cash equivalents | 4,213,676 | (319,409) |
| Cash and cash equivalents at beginning of period | 3,293,983 | 3,613,392 |
| Cash and cash equivalents at end of period | $ 7,507,659 | $ 3,293,983 |
| **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 | 26,785 | 122,176 |
| Stock issued for settlement of accrued bonus | (364,910) | — |
| Purchase of property and equipment under capital lease | 227,147 | — |
| Incentive from landlord | 710,000 | — |
| **Supplemental cash flow information** | | |
| Cash paid for interest | $ 1,109,359 | $ 935,004 |

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

## Note 1. Description of Business

HTG Molecular Diagnostics, Inc. (the "Company") is a commercial stage company that develops and markets products and services based on proprietary technology that facilitates the routine use of targeted molecular profiling. The Company derives revenue from services provided by its VERI/O laboratory and sales of the Company's automation systems and integrated next-generation sequencing-based HTG EdgeSeq assays.

The Company operates in one segment and its customers are primarily located in the United States. For the year ended December 31, 2016, approximately 16% of the Company's revenue was generated from sales originated by customers located outside of the United States, compared with 13% for the year ended December 31, 2015.

### 2015 Reverse Stock Split

On April 27, 2015, the Company effected a one-for-107.39 reverse stock split of its outstanding common stock. All applicable common share and per common share information has been retroactively adjusted to reflect the effect of this reverse stock split. The reverse stock split did not change the number of shares of convertible preferred stock outstanding, but did affect the conversion ratios associated with the convertible preferred stock.

### Initial Public Offering

On May 11, 2015, the Company successfully completed its initial public offering ("IPO"), in which the Company sold 3,570,000 shares of common stock at $14.00 per share for total gross proceeds of approximately $50 million. An additional 90,076 shares of common stock were subsequently sold pursuant to the partial exercise by the underwriters of their over-allotment option resulting in additional gross proceeds of approximately $1.3 million. After underwriters' fees and commissions and other expenses of the offering, the Company's aggregate net proceeds were approximately $45.4 million. All outstanding shares of the Company's redeemable convertible preferred stock converted into shares of common stock in connection with the IPO. Following the IPO, there were no shares of preferred stock outstanding.

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

### Accounting Principles

The financial statements and accompanying notes were prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

### 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 Annual Report on Form 10-K with the Securities and Exchange Commission ("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 $115.6 million. As of December 31, 2016, the Company had available cash, cash equivalents and investments in short term available-for-sale securities of approximately $11.8 million, and had current liabilities of approximately $10.0 million plus an additional $14.0 million in long-term liabilities primarily attributable to its growth term loan and NuvoGen obligation. 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 at all, 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. In addition, if the Company defaults under its term loan agreement, its lenders could foreclose on its assets, including substantially all of its cash which is held in accounts with its lenders.

**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 U.S. 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, provisions for doubtful accounts, inventory obsolescence and inventory valuation. Actual results could materially differ from those estimates.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash and cash equivalents. Cash and cash equivalents consist of cash on deposit with financial institutions, money market instruments and high credit quality corporate debt securities purchased with a term of three months or less.

**Accounts Receivable**

Accounts receivable represent valid claims against debtors. Management reviews accounts receivable regularly to determine, using the specific identification method, if any receivable amounts will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value. As of both December 31, 2016 and 2015, there were no receivable amounts requiring an allowance for doubtful accounts. The Company had a recovery of $35,000 against previously recorded bad debt expense and no write offs of uncollectible amounts for the year ended December 31, 2016. Bad debt expense, net of recoveries, was $44,854 for the year ended December 31, 2015.

**Investments**

The Company classifies its debt securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive loss, net of tax. Realized gains, realized losses and declines in value of securities judged to be other-than-temporary, are included in other income (expense) within the statements of operations. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Interest earned on all securities is included in other income (expense) within the statements of operations. Investments in securities with maturities of less than one year, or where management's intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present value of

cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against other income (expense).

**Fair Value of Financial Instruments**

The carrying value of financial instruments classified as current assets and current liabilities approximate fair value due to their liquidity and short-term nature. Investments that are classified as available-for-sale are recorded at fair value, which was determined using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The carrying amount of the Company's asset-secured growth capital term loan (the "Growth Term Loan") was estimated using Level 3 inputs and approximate fair value since the interest rate approximates the market rate for debt securities with similar terms and risk characteristics.

Fair value measurements are based on the premise that fair value is an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the following three-tier fair value hierarchy has been used in determining the inputs used in measuring fair value:

Level 1 – Quoted prices in active markets for identical assets or liabilities on the reporting date.

Level 2 – Pricing inputs are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Pricing inputs are generally unobservable and include situations where there is little, if any, market activity for the investment. The inputs into the determination of fair value require management's judgment or estimation of assumptions that market participants would use in pricing the assets or liabilities. The fair values are therefore determined using factors that involve considerable judgment and interpretations, including but not limited to private and public comparables, third-party appraisals, discounted cash flow models, and fund manager estimates.

**Inventory, net**

Inventory, consisting of raw materials, work in process and finished goods, is stated at the lower of cost (first-in, first-out) or market. Cost is determined using a standard cost system, whereby the standard costs are updated periodically to reflect current costs and market represents the lower of replacement cost or estimated net realizable value. The Company reserves or writes down its inventory for estimated obsolescence or inventory in excess of reasonably expected near term sales or unmarketable inventory, in an amount equal to the difference between the cost of inventory and the estimated market value, based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by the Company, additional inventory write-downs may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not reversed subsequently to income, even if circumstances later suggest that increased carrying amounts are recoverable.

For the year ended December 31, 2016, the Company wrote off HTG Edge Reader inventory previously reserved of $210,183 and additional HTG Edge Reader-related inventory totaling $360,194. Additional reserves were recorded for excess HTG Edge inventory of $133,244 and the reserve for shrinkage and excess inventory was increased by $62,927. An additional $167,100 of non-reader related inventory was written off directly to cost of revenue for the year ended December 31, 2016.

For the year ended December 31, 2015, the Company recorded an increase in the inventory reserve within cost of revenue of $230,050, to adjust for estimated shrinkage and excess inventory.

Equipment that is under evaluation for purchase remains in inventory as the Company maintains 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 need to be extended beyond that period. However, in no case will the evaluation period exceed one year. If the customer has not purchased the equipment or entered into a reagent rental agreement with the Company after evaluating for one year, the equipment is returned to the Company or the customer is allowed to continue use of the equipment, in which case the equipment is written off to selling, general and administrative expense in the statement of operations. HTG EdgeSeq instruments at customer locations under evaluation agreements are included in finished goods inventory. Finished goods inventory under evaluation as of December 31, 2016 was $185,557 compared to $632,216 as of December 31, 2015.

**Property and Equipment, net**

Property and equipment are stated at historical cost and depreciated over their useful lives, which range from three to five years, using the straight-line method. Field equipment is amortized using the straight-line method over the lesser of the period of the related reagent rental agreement or the estimated useful life. Leasehold improvements are amortized using the straight-line method over the lesser of the remaining lease term or the estimated useful life.

Certain leasehold improvements constructed by the landlord of the Company's Tucson, AZ facilities as an incentive for the Company to extend its leases are included in leasehold improvements on the balance sheets as of December 31, 2016. The total cost of the improvements constructed by the landlord of $710,000 was capitalized when construction was completed in February 2016, and is being amortized 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 balance sheets and is being accreted over the lease term as a reduction of rent expense.

Depreciation and leasehold improvement amortization expense was $1,473,778 for the year ended December 31, 2016, and $662,562 for the year ended December 31, 2015.

Costs incurred in the development and installation of software for internal use are expensed or capitalized, depending on whether they are incurred in the preliminary project stage (expensed), application development stage (capitalized), or post-implementation stage (expensed). Amounts capitalized following project completion are amortized on a straight-line basis over the useful life of the developed asset, which is generally three years. There was $283 and $0 amortization expense for capitalized software costs for the years ended December 31, 2016 and 2015, respectively.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to the estimated undiscounted future cash flows expected to be generated by the asset group. If the carrying amount of an asset group exceeds its estimated future cash flow, an impairment charge is recognized in the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. Although the Company has accumulated losses since inception, the Company believes the future cash flows will be sufficient to exceed the carrying value of the Company's long-lived assets. There were no impairments of long-lived assets during the years ended December 31, 2016 or 2015.

**Stock Issuance Costs**

Certain costs incurred in connection with the issuance of the Company's redeemable convertible preferred stock (the "Convertible Preferred Stock") prior to the IPO were being deferred and accreted. Stock issuance costs have historically been accreted to distributions in excess of capital using the effective interest method. The Company recognized accretion costs of 35,046 for the year ended December 31, 2015. There were no accretion costs for the year ended December 31, 2016. Upon automatic conversion of the Convertible Preferred Stock to common stock in connection with the closing of the IPO in May 2015, issuance costs were no longer accreted.

**Deferred Financing Costs and Debt Discounts**

Certain costs incurred in connection with the Growth Term Loans have been deferred and are being amortized. Debt issuance costs and debt discount are being presented as a direct deduction from term loan payable – non-current, net of discount and debt issuance costs in the accompanying balance sheets and are being amortized over the term of the Growth Term Loans using the effective interest method. The Company has recorded approximately $24,909 and $52,377 of deferred financing costs in the accompanying balance sheets as of December 31, 2016 and 2015, respectively. Deferred financing cost amortization expense for the years ended December 31, 2016 and 2015 was $27,468 and $22,754, respectively. The Company has recorded approximately $238,469 and $352,415 of discounts associated with Growth Term Loan A and Growth Term Loan B in the accompanying balance sheets as of December 31, 2016 and 2015, respectively. Amortization of the discounts associated with the Growth Term Loans totaled $249,868 and $170,954 for the years ended December 31, 2016 and 2015, and is included in interest expense in the accompanying statements of operations.

Prior to the IPO, costs incurred in connection with the issuance of notes under the Company's two note and warrant purchase agreements dated December 30, 2014 (the "Note Agreements") were capitalized and amortized over the term of the Note Agreements using the straight-line accretion method, which approximated the effective interest method in this instance. Amortization of the discount and issuance costs on the Note Agreements was $0 and $112,134 for the years ended December 31, 2016 and 2015, and is included in interest expense in the accompanying statements of operations. 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 recorded a loss on settlement of convertible debt of $705,217, comprising $651,606 to write off unamortized discount and $53,611 to write off unamortized deferred financing costs relating to the convertible notes which were settled with common stock at the IPO, in the accompanying statements of operations for the year ended December 31, 2015.

**Deferred Offering Costs**

Deferred offering costs represent legal, accounting and other direct costs related to stock offering transactions. Deferred offering costs of $49,630 included as non-current assets in the accompanying December 31, 2016 balance sheets represent legal costs incurred during the year ended December 31, 2016 by the Company in contemplation of the issuance of additional shares in a future financing transaction. In accounting for the IPO in May 2015, deferred offering costs of approximately $2.3 million are shown, along with underwriters' fees paid, net against IPO proceeds received. As a result of this transaction, there were $0 deferred offering costs in the accompanying balance sheets as of December 31, 2015.

**Deferred Revenue**

Deferred revenue represents cash receipts for products or services to be provided in future periods, including up-front fees received relating to custom assay development and collaboration agreements. When products are delivered or data is provided to customers for sample processing services rendered, deferred revenue is recognized as earned. Up-front fees received for customer assay development and collaboration agreements are recognized as services are performed on a proportional performance basis.

**Revenue Recognition**

The Company recognizes revenue from the sale of instruments, consumables, sample processing, custom assay development and collaboration services when the following four basic criteria are met: (1) a contract has been entered into with a customer or persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed or determinable, and (4) collectability is reasonably assured.

*Sale of instruments and consumables*

The Company had product revenue consisting of revenue from the sale of instruments and consumables for the years ended December 31, 2016 and 2015 as follows:

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Instruments | $ 522,813 | $ 789,231 |
| Consumables | 2,237,129 | 2,742,797 |
| Total product sales | $ 2,759,942 | $ 3,532,028 |

Instrument product revenue is generally recognized upon installation and calibration of the instrument by field service engineers, unless the customer has specified any other acceptance criteria. The sale of instruments and related installation and calibration are considered to be one unit of accounting, as instruments are required to be professionally installed and calibrated before use. Installation generally occurs within a month of shipment.

Consumables are considered to be separate units of accounting as they are sold separately. Consumables revenue is recognized upon transfer of ownership. The Company's standard terms and conditions provide that no right of return exists for instruments or consumables, unless replacement is necessary due to delivery of defective or damaged products. Shipping and handling fees charged to the Company's customers for instruments and consumables shipped are included in the statements of operations as part of product revenue. Shipping and handling costs for sold products shipped to the Company's customers are included on the statements of operations as part of cost of revenue.

When a contract involves multiple elements, the items included in the arrangement, referred to as deliverables, are evaluated to determine whether they represent separate units of accounting in accordance with ASC 605-25, *Revenue Recognition – Multiple-Element Arrangements ("*ASC 605-25"). The Company performs this evaluation at the inception of an arrangement and as each item

is delivered in the arrangement. Generally, the Company accounts for a deliverable (or a group of deliverables) separately if the delivered item has stand-alone value to the customer and delivery or performance of the undelivered item or service is probable and substantially in the Company's control. When multiple elements can be separated into separate units of accounting, arrangement consideration is allocated at the inception of the arrangement, based on each unit's relative selling price, and recognized based on the method most appropriate for that unit.

The Company provides instruments to certain customers under reagent rental agreements. Under these agreements, the Company installs instruments in the customer's facility without a fee and the customer agrees to purchase consumable products at a stated price over the term of the agreement; in some instances, the agreements do not contain a minimum purchase requirement. Terms range from several months to multiple years and may automatically renew in several month or multiple year increments unless either party notifies the other in advance that the agreement will not renew. This represents a multiple element arrangement and because all consideration under the reagent rental agreement is contingent on the sale of consumables, no consideration has been allocated to the instrument and no revenue has been recognized upon installation of the instrument. The Company expects to recover the cost of the instrument under the agreement through the fees charged for consumables, to the extent sold, over the term of the agreement.

In reagent rental agreements, the Company retains title to the instrument and title is transferred to the customer at no additional charge at the conclusion of the initial arrangement. Because the pattern of revenue from the arrangement cannot be reasonably estimated, the cost of the instrument is amortized on a straight-line basis over the term of the arrangement, unless there is no minimum consumable product purchase in which case the instrument would be expensed as cost of revenue. Cost to maintain the instrument while title remains with the Company is charged to selling, general and administrative expense as incurred.

The Company offers customers the opportunity to purchase separately-priced extended warranty contracts to provide for service upon conclusion of the standard one-year warranty period. The revenue from these contracts is recorded as a component of deferred revenue in the accompanying balance sheets at the inception of the contract and is recognized as revenue over the contract service period.

*Service Revenue*

The Company enters into custom assay development agreements and collaborative agreements that may generate up-front fees and subsequent payments which might be earned upon completion of development-related services. The Company is able to estimate the total cost of services under these arrangements and recognizes revenue using a proportional performance revenue recognition model, under which revenue is recognized as performance occurs based on the delivery of the relative outputs under the respective agreement. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangements. Revenue recognized at any point in time is limited to cash received and amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. From period to period, collaboration, companion diagnostic program and custom assay development revenue can fluctuate substantially based on the achievement of development-related services.

*Sample Processing Services*

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

*Multiple-Element Arrangements*

Contracts which combine one or more services, or services with sales of products or consumables are accounted for as multiple element arrangements under ASC 605-25, as described under sale of instruments and consumables above. Anticipated losses, if any, on contracts are charged to earnings as soon as they are identified. Anticipated losses cover all costs allocable to contracts. Revenue arising from claims or change orders is recorded either as income or as an offset against a potential loss only when the amount of the claim can be estimated and its realization is probable.

*Other Revenue*

Other revenue includes grant revenue. Grant revenue is earned when expenditures relating to the projects under these awards are incurred.

**Product Warranty**

The Company generally provides a one-year warranty on its HTG Edge and HTG EdgeSeq systems covering the performance of system hardware and software in conformance with customer specifications under normal use and protecting against defects in materials and workmanship. The Company may, at its option, replace, repair or exchange products covered under valid warranty claims. A provision for estimated warranty costs is recognized at the time of sale, through cost of revenue, based upon recent historical experience and other relevant information as it becomes available. The Company continuously assesses the adequacy of its product warranty accrual by reviewing actual claims and adjusts the provision as needed. Due to a lack of historical data and a low rate of warranty claims, the Company had not recorded any liability for product warranty prior to 2015.

**Research and Development Expenses**

Research and development expenses represent both costs incurred internally for research and development activities and costs incurred externally to fund research activities. All research and development costs are expensed as incurred.

**Advertising**

All costs associated with advertising and promotions are expensed as incurred. Advertising and promotion expense was $49,022 and $11,761 for the years ended December 31, 2016 and 2015, respectively, and is included as a component of selling, general and administrative expenses on the accompanying statements of operations.

**Stock-Based Compensation**

The Company incurs stock-based compensation expense relating to grants of restricted stock units ("RSUs") and stock options to employees, consultants and non-employee directors and its employee stock purchase plan ("ESPP").

The Company recognizes expense for stock-based awards to employees and non-employee directors based on the fair value of awards on the date of grant. The fair value of RSUs is based on the quoted market price of the Company's common stock on the date of grant. The fair value of ESPP rights and stock options granted pursuant to the Company's equity incentive plans is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value utilizing the Black-Scholes option pricing model is affected by the fair value of the Company's stock price and several assumptions, including volatility, expected term, risk-free interest rate, and dividend yield. Generally, these assumptions are based on historical information and judgment is required to determine if historical trends may be indicators of future outcomes.

The Company recognizes compensation cost for stock-based awards with service conditions that have a graded vesting schedule on a straight-line basis over the requisite service period. However, the amount of compensation cost recognized at any time generally equals the portion of grant-date fair value of the award that is vested at that date, net of estimated forfeitures. Forfeitures are revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates and an adjustment to stock-based compensation expense will be recognized at that time. Changes to assumptions used in the Black-Scholes option pricing model and the forfeiture rate could significantly impact the compensation expense recognized by the Company. The Company considered its historical experience of pre-vesting option forfeitures as the basis to arrive at its estimated pre-vesting option forfeiture rates of 11% and 17% per year for the years ended December 31, 2016 and 2015, respectively. The Company would report cash flows resulting from tax deductions in excess of the compensation cost recognized from those options (excess tax benefits) as financing cash flows, if applicable.

For stock-based payments to consultants, the fair value of the stock-based award is used to measure the transaction, as the Company believes this to be a more reliable measure of fair value than the services received. The fair value of the award is measured at the fair value on the date that the commitment for performance by the nonemployee has been reached or performance is complete. Stock-based compensation to nonemployees is recognized as expense over the requisite service period, which is generally the vesting period for awards, on a straight-line basis.

**Income Taxes**

The Company accounts for income taxes under the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts and tax base of assets and liabilities using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established against net deferred tax assets for the uncertainty it presents of the Company's ability to use the net deferred tax assets, in this case, primarily carryforwards of net operating tax losses and research and development tax credits. In assessing the realizability of net deferred tax assets, the Company assesses the likelihood that net deferred tax assets will be recovered from future taxable income, and to the extent that recovery is not "more likely than not" or there is insufficient operating history, a valuation allowance is established. The Company records the valuation allowance in the period the

Company determines that it is more likely than not that net deferred tax assets will not be realized. For the years ended December 31, 2016 and 2015, the Company has provided a full valuation allowance for all net deferred tax assets due to their current realization being considered remote in the near term. Uncertain tax positions taken or expected to be taken in a tax return are accounted for using the more likely than not threshold for financial statement recognition and measurement. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. No material uncertain tax positions have been identified or recorded in the financial statements as of December 31, 2016 and 2015.

**Comprehensive loss**

Comprehensive loss includes certain changes in equity that are excluded from net loss. Specifically, unrealized gains and losses on short and long-term available-for-sale investments are included in comprehensive loss.

**Concentration Risks**

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents 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 assay development services and contracted research and development services primarily to biopharmaceutical companies, academic institutions and molecular labs. The Company routinely assesses the financial strength of its customers and credit losses have been minimal to date.

The top two customers accounted for 29% and 12% of the Company's revenue for the year ended December 31, 2016, compared with 38% and 7% for the year ended December 31, 2015. The Company derived 0% and 8% of its total revenue from grants and contracts, primarily from one organization during the years ended December 31, 2016 and 2015. The largest two customers accounted for approximately 28% and 15% of the Company's net accounts receivable as of December 31, 2016. The largest two customer account for approximately 32% and 25% of the Company's net accounts receivable at December 31, 2015.

The Company currently relies on a single supplier to supply a subcomponent used in the HTG EdgeSeq processors and a second supplier to provide raw materials used in its HTG EdgeSeq proprietary panels. A loss of either of these suppliers could significantly delay the delivery of products or the completion of services to be performed by our VERI/O laboratory, which in turn would materially affect the Company's ability to generate revenue.

**New 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 U.S. 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 U.S. GAAP.

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

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

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

The new revenue standard and the standards that amend it are 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 in the initial stages of evaluating the effect of adoption of ASU 2014-09 on its financial statements and continues to evaluate the available transition methods. The Company has begun assessing the standard as it will pertain to its collaborative arrangements with multiple deliverables, which includes performing a detailed review of its existing key contracts and comparing historical accounting policies and practices to the new standard. The Company will continue its evaluation of the standards update through the date of adoption.

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 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 notions 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,* ("ASU 2016-02"). Under this standard, which applies to both lessors and lessees, lessees will be required to recognize for all leases (except for 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 effect of adoption of this standard on our financial statements will depend on the leases existing at January 1, 2018. Based on the Company's preliminary assessment of its office and equipment leases that are in place as of December 31, 2016, however, and considering the practical expedients, the Company expects that adoption of ASU 2016-02 will not have a material effect on its statements of operations, will result in a gross-up on its balance sheets of less than $3.0 million relating to office and equipment leases and will have no effect on its statements of cash flows. The Company will continue to assess the new guidance and its potential applicability to the other existing agreements, or to new agreements that it may enter into subsequent to December 31, 2016, through the date of adoption.

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 expect the immediate recognition of income taxes under this standard to have a material impact on its statements of operations as it has recorded a full valuation allowance on all deferred tax assets. The Company is currently evaluating the impact of the remainder of this guidance 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 carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The standard 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, given the high credit quality of the obligors to its available-for-sale debt securities and its limited history of bad debt expense relating to trade accounts receivable.

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. When considering the activity within the Company's statements of

cash flow as of the years ended December 31, 2016 and 2015, the Company does not believe the adoption of this standard will have a significant impact on its financial statements.

**Note 3. Inventory**

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

| | December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Raw materials | $ 1,222,437 | $ 1,274,840 |
| Work in process | 1,762 | — |
| Finished goods | 557,161 | 1,210,780 |
| Total gross inventory | 1,781,360 | 2,485,620 |
| Less inventory allowance | (270,307) | (284,319) |
| | $ 1,511,053 | $ 2,201,301 |

**Note 4. Fair Value**

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

| | Balance at December 31, 2016 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Asset included in: | | | | |
| Cash and cash equivalents | | | | |
| Money market securities | $ 6,443,102 | $ — | $ — | $ 6,443,102 |
| Investments available-for-sale at fair value | | | | |
| U.S. government obligations | $ 1,300,663 | $ — | $ — | $ 1,300,663 |
| Corporate debt securities | $ — | $ 3,004,238 | $ — | $ 3,004,238 |

| | 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 were no other financial instruments subject to fair value measurement on a recurring basis. Transfers to and from Levels 1, 2 and 3 are recognized at the end of the reporting period. There were no transfers between levels for the years ended December 31, 2016 and 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 and liabilities 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 either of the years ended December 31, 2016 or 2015.

**Note 5. Available for Sale Securities**

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. Initial investment in available-for-sale securities was made during the quarter ended June 30, 2015 as a result of funding received through the IPO. The following is a summary of the Company's available-for-sale securities at December 31, 2016:

| | December 31, 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 | $ 1,300,151 | $ 512 | $ — | $ 1,300,663 |
| Corporate debt securities | 3,005,840 | — | (1,602) | 3,004,238 |
| Total available-for-sale securities | $ 4,305,991 | $ 512 | $ (1,602) | $ 4,304,901 |

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

| | 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 gain (loss) on short and long-term available-for-sale securities in other comprehensive income (loss) totaled $40,267 and $(41,357), for the years ended December 31, 2016 and 2015, respectively.

Contractual maturities of debt investment securities at December 31, 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.

| | 2016 |
|---|---|
| Maturing in one year or less | $ 4,304,901 |
| Maturing in one to three years | — |
| Total available-for-sale securities | $ 4,304,901 |

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 December 31, 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 | 1,304,738 | (1,602) | — | — | 1,304,738 | (1,602) |
| Total available-for-sale securities with unrealized losses | $ 1,304,738 | $ (1,602) | $ — | $ — | $ 1,304,738 | $ (1,602) |

For debt securities, the Company determines whether it intends to sell or if it is more likely than not that it will be required to sell impaired securities. This determination considers current and forecasted liquidity requirements, regulatory and capital requirements and securities portfolio management. For all impaired debt securities for which there was no intent or expected requirement to sell, the

evaluation considers all available evidence to assess whether it is likely the amortized cost value will be recovered. The Company conducts a regular assessment of its debt securities with unrealized losses to determine whether securities have other-than-temporary impairment considering, among other factors, the nature of the securities, credit rating or financial condition of the issuer, the extent and duration of the unrealized loss, expected cash flows of underlying collateral, market conditions and whether the Company intends to sell or it is more likely than not the Company will be required to sell the debt securities. The Company did not have any other-than-temporary impairment in its U.S. Treasury securities, obligations of U.S. government agencies or corporate debt securities for the years ending December 31, 2016 and 2015.

**Note 6. Property and Equipment**

Property and equipment, net consists of the following:

| | December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Office equipment | $ 447,580 | $ 257,296 |
| Leasehold improvements | 1,847,378 | 224,061 |
| Laboratory and manufacturing equipment | 2,659,621 | 2,442,191 |
| Field equipment | 131,096 | 180,355 |
| Software | 150,451 | 140,248 |
| Construction in progress | 176,963 | 175,501 |
| | 5,413,089 | 3,419,652 |
| Less: accumulated depreciation and amortization | (2,142,892) | (1,487,439) |
| | $ 3,270,197 | $ 1,932,213 |

During the years ended December 31, 2016 and 2015, the Company retired fully-depreciated property and equipment with a gross carrying value of $589,179 and $1,066,246, respectively. These assets were previously contained in office equipment, leasehold improvements and laboratory and manufacturing equipment.

**Note 7. Accrued Liabilities**

Accrued liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Employee compensation and benefits | $ 1,088,773 | $ 1,240,314 |
| Employee compensation for future absences | 173,533 | 154,107 |
| Interest | 82,591 | 77,917 |
| Professional fees | 79,029 | 140,385 |
| Other | 246,360 | 302,545 |
| | $ 1,670,286 | $ 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. With the August 2015 amendment, the interest-only payment period for the Growth Term Loan was extended 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 the Growth Term Loan. Growth Term Loan A and B bear interest at the fixed rates of 8.5% and 8.75%, respectively, and mature in September 2018. The amended agreement includes the following prepayment fees: (i) 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 (ii) 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 Growth Term Loan requires the Company to maintain compliance with specific operating and 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. If the Company were to default under the Growth Term Loan, its lenders could foreclose on its assets, including substantially all of its cash, which is held in accounts with its lenders.

The principal repayments due under the term loan as of December 31, 2016, are as follows:

| | |
|---|---|
| 2017 | $ 6,389,782 |
| 2018 | 5,163,822 |
| Total Growth Term Loan payments | 11,553,604 |
| Less discount and deferred financing costs | (263,378) |
| Plus final fee premium | 488,693 |
| Total Growth Term Loan, net | $ 11,778,919 |

Following the August 2015 amendment, the final payment percentage on the Growth Term Loan was increased to 4.75%. After amendment, the final fee premium relating to Growth Term Loan A is $522,500. The final fee premium relating to the Growth Term Loan B is $237,500. Each final fee premium is being amortized to interest expense, using the effective interest method, over the term of the related Growth Term Loan tranche. Total Growth Term Loan final fee premium amortization for the year ended December 31, 2016 was $273,786, compared to $158,707 for the year ended December 31, 2015.

The Company received Growth Term Loan A proceeds net of a $0.3 million original issuance discount. In addition, in connection with 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, which resulted in the recording of a warrant discount. Upon the completion of the 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 original issuance discount and warrant discount are being amortized, using the effective interest method, over the term of the Growth Term Loan A.

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 this 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.

Total amortization expense for the Growth Term Loan A and B warrant discounts and the Growth Term Loan A original issuance discount was $249,868 and $170,954 for the years ended December 31, 2016 and 2015, respectively, and is included in interest expense in the accompanying statements of operations.

The Company has also recorded approximately $24,909 and $52,377 of deferred financing costs net of the related debt in the accompanying balance sheets as of and December 31, 2016 and 2015, respectively, in accordance with ASU 2015-03, which was adopted on January 1, 2016. Growth Term Loan deferred financing cost amortization expense was $27,468 and $22,754 for the years ended December 31, 2016 and 2015, respectively, and is included in interest expense in the accompanying statements of operations.

The June 2016 Growth Term Loan 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.

**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 initial public offering 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 IPO in May 2015. The Company recorded a $741,828 discount for the estimated fair value of warrants issued in connection with the debt and $75,520 of deferred financing costs incurred in connection with the issuance of notes under the Note Agreements. Amortization of the Note Agreement discount and deferred financing fees associated with the Note Agreements was $0 and $112,134 for the years ended December 31, 2016 and 2015, respectively, which was included in interest expense in the accompanying statements of operations.

*Settlement of Convertible Debt upon IPO Closing*

Upon closing of the IPO in May 2015, all outstanding principal ($4.5 million) and accrued interest under the convertible notes issued pursuant to the first Note Agreement was converted into 324,591 shares of common stock at a conversion price of $14.00 per share. The Company evaluated the terms of the Note Agreement at inception and concluded that it should be accounted for as share settled debt as it falls within the scope of ASC 480, *Distinguishing Liabilities from Equity*. While the issued Note Agreements contain multiple events that could trigger settlement at different values, the Company evaluated all of the possible outcomes and considered the qualified initial public offering outcome to be predominant at more than a 50% probability of occurrence. 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 recognized a loss on settlement of debt of $705,217 in the accompanying statements of operations for the year ended December 31, 2015. The value of the debt adjusted to the value of the common stock paid was reclassified from debt to equity.

**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 initially paid NuvoGen 5,587 shares of the Company's common stock, fixed payments of $740,000 over the first two years of the agreement and agreed to pay NuvoGen 6% of its 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, the Company became 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. No accrued revenue-based payments have been deferred through December 31, 2016. Beginning in 2018, we are obligated to pay the greater of $400,000 or 6% of the Company's applicable annual revenues, plus amounts, if any, deferred in 2017 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 is currently non-interest bearing and was, but is no longer, secured by certain patents and trademarks.

Pursuant to the closing of the Growth Term Loan 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, $543,750 has been paid to NuvoGen toward the remaining obligation.

The remaining minimum principal payments due to NuvoGen at December 31, 2016 are 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:

| | |
|---|---|
| 2017 | $ 800,000 |
| 2018 | 400,000 |
| 2019 | 400,000 |
| 2020 | 400,000 |
| 2021 | 400,000 |
| 2022 and beyond | 6,298,743 |
| Total NuvoGen obligation payments | 8,698,743 |
| Less discount | (76,636) |
| Total NuvoGen obligation, net | $ 8,622,107 |

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 $76,636 and $283,621 at December 31, 2016 and 2015, respectively. Discount accreted during the years ended December 31, 2016 and 2015 was $206,985, and $281,013, respectively.

**Illumina, Inc. Agreement**

The Company entered into a development and component supply agreement in 2014 with Illumina, Inc. ("Illumina") 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 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, among other things, 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, which relates to the Company's HTG EdgeSeq ALK*Plus* Assay, now in development. 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 none of these regulatory milestones have been reached through December 31, 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 intended for laboratories with low volume sample throughput and further is intended to automate assays designed for the Company's V2 chemistry. This instrument design and development program 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 until the Company makes the decision to resume further external development efforts. We anticipate resumption of development efforts in 2017 as our V2 chemistry nears commercialization. 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 statements of operations relating to Invetech development fee installments was $2.3 million and $0.3 million for the years ended December 31, 2016 and 2015, respectively.

**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 December 31, 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. 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 or 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 or 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. Because the custom assay fees are contingent upon completion of each individual phase of the design project and the decision by BMS to proceed to the next phase, the amount recognized will be limited to that which BMS is contractually obligated to pay upon completion of that phase.

For the year ended December 31, 2016, $189,442 was recognized under the agreement as service revenue in the statements of operations and $160,106 was recognized as deferred revenue in the balance sheets as of December 31, 2016. No revenue or deferred revenue was recognized relating to this BMS agreement for the year ended December 31, 2015.

**Merck KGaA Agreement**

In October 2016, the Company entered a Master CDx Agreement, or master agreement, with Merck KGaA, Darmstadt, Germany, ("Merck KGaA") to serve as the basis for one or more project agreements to develop, seek regulatory approval for, and commercialize companion diagnostics for Merck KGaA drug candidates and corresponding therapeutics. Concurrently, the parties entered into a first project agreement under the master agreement concerning the Company's sequencing-based DLBCL cell of origin assay ("DLBCL Assay") and Merck KGaA's investigational drug, M7583 (the "Project").

The Project has three stages aligned with timelines and outcomes of M7583 development. During stages 1 and 2, the Company will perform specified DLBCL Assay development activities. In stage 3, the Company will obtain applicable regulatory approvals on the DLBCL Assay and make it commercially available in the United States and certain other jurisdictions.

Stages 2 and 3 each have an up-front payment and all stages of the Project have milestone-based payments. The Company is eligible to receive up to a total of approximately $1,850,000 over the next five years and $9,900,000 over a period of approximately nine years in fixed or determinable contract consideration comprising up-front and milestone payments. In addition, during stages 1 and 2 of the Project, the Company will sell DLBCL Assay kits and/or perform sample processing services upon request of, and as instructed by, Merck KGaA. The up-front and milestone-based payments could be delayed due to the risks of completing development activities and obtaining regulatory approvals within projected timeframes.

Merck KGaA may terminate the Project by providing 90 days' prior written notice to the Company, at which point Merck KGaA will reimburse HTG for costs incurred during the termination period, of an amount not to exceed non-cancellable, non-reimbursable expenses, and HTG will reimburse Merck KGaA for any costs that have been prepaid without being incurred prior to termination. Further, either party may also terminate the agreement upon the other party's material breach that remains uncured for 45 days or upon the other party's bankruptcy.

The agreement is a multiple-element arrangement under ASC 605-25. Kit sales and sample processing services have been 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. The remaining deliverables, including licenses to HTG patents and research and development services, do not have standalone value and are combined into one unit of accounting.

Under ASC 605-25, fixed or 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 or determinable contract consideration will be allocated to one deliverable, which is the research and development services.

Non-refundable up-front payments will be received at the initiation of stages 2 and 3. These payments will be recognized as revenue over the period that the research services are expected to occur. All other payments are contingent upon completion of milestones. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the Project. Revenue recognized at any point in time is limited to cash received and amounts contractually due. The Company did not receive any payments and did not recognize any revenue related to the Project for the year ended December 31, 2016.

**Other Agreements With Related-Parties**

Refer to Note 16 below for discussion of agreements with related parties.

**Note 10. Net Loss Per Share**

Net loss attributable to common stockholders per share 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 attributable to common stockholders per share 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:

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Numerator: | | |
| Net loss | $ (26,039,550) | $ (21,397,791) |
| Accretion of stock issuance costs | — | (35,046) |
| Accretion of discount on Series E warrants | — | (127,616) |
| Series D and E Convertible Preferred Stock dividends | — | (1,165,932) |
| Net loss attributable to common stockholders | $ (26,039,550) | $ (22,726,385) |
| Denominator: | | |
| Weighted-average common shares outstanding-basic and diluted | 7,113,075 | 4,518,499 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (3.66) | $ (5.03) |

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

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Options to purchase common stock | 1,161,705 | 736,645 |
| Common stock warrant | 219,723 | 169,099 |
| Restricted stock units | 355,499 | 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 (see Note 8), the Company issued to the two-lender syndicate 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 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 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 originally 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.

On December 30, 2014, in connection with the Company's Note Agreements (see Note 8) the Company agreed to issue warrants ("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 on January 15, 2015. The warrants provide for cashless exercise at the option of the holders, and 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 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 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 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 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 for the periods presented:

| | Shares of Common Stock Underlying Warrants at December 31, | | | |
|---|---|---|---|---|
| Series of Warrants | 2016 | 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 year ended December 31, 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 statements of operations. There was no similar loss recorded for the year ended December 31, 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 IPO. As such, the fair value of the preferred stock warrant liability was $0 at both December 31, 2016 and 2015.

**Note 12. Redeemable Convertible Preferred Stock**

On February 4, 2014, the Company entered into the Series E Preferred Stock and Warrant Purchase Agreement ("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 ("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 gross 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, but was replaced by an alternative financing in the form of subordinated convertible promissory notes to be issued under the Note Agreements (see Note 8).

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

The Series D and Series E Stock liquidation preference was equal to two times the original issue price of the Series D Stock or Series E, 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 IPO in May 2015.

| 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 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 had 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 years ended December 31, 2016 and 2015 was $0 and $127,616, 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 the 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 (see Note 8), 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 in May 2015.

**Note 13. Stockholders' Equity (Deficit)**

**Common Stock**

The Company amended its certificate of incorporation on May 11, 2015, to decrease the number of authorized shares 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

December 31, 2016, 7,939,967 and 7,938,571 shares were issued and outstanding, respectively. As of December 31, 2015, 6,845,638 and 6,844,242 shares were issued and outstanding, respectively.

Each share of common stock is entitled to one vote. The shares of common stock have no preemptive or conversion rights, no redemption or sinking fund provisions, no liability for further call or assessment, and are not entitled to cumulative voting rights.

**Treasury Stock**

Shares of common stock repurchased by the Company are recorded as treasury stock and result in an increase of stockholders' equity (deficit) on the balance sheets. Reacquired common shares may be retired by resolution of the board of directors and resume the status of authorized and unissued common shares. There was no new treasury stock activity for the years ended December 31, 2016 and 2015. In January 2017, the Company's Board of Directors retired 1,396 shares of treasury stock to be returned to the status of authorized and unissued shares of the Company's common stock.

**Preferred Stock**

Pursuant to the Company's certificate of incorporation the Company has been 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. The Board of Directors can determine voting power for each series issued, as well as designation, preferences, and relative, participating, optional or other rights and such qualifications, limitations or restrictions thereof.

**Stock-based Compensation**

The Company incurs stock-based compensation expense relating to the grants of RSUs and stock options to employees and non-employee directors and through its employee stock purchase plan. Amounts recognized in the statements of operations with respect to the Company's stock-based compensation were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Selling, general and administrative | $ 651,034 | $ 367,000 |
| Research and development | 195,685 | 38,426 |
| Cost of revenue | 56,865 | — |
| | $ 903,584 | $ 405,426 |

The Company initially established the 2001 Stock Option Plan ("2001 Plan"), which included incentive and nonqualified stock options and restricted stock to be granted to directors, officers, employees, consultants and others. The 2001 Plan terminated and no further awards were granted under the 2001 Plan upon the effective date of the Company's 2011 Equity Incentive Plan ("2011 Plan").

In February 2014, pursuant to the Series E Agreement, the number of shares reserved under the 2011 Plan was increased to 20% of the total outstanding shares of the Company calculated on a fully diluted basis. The shares reserved under the 2011 Plan were required to be kept at that percentage with each subsequent equity financing. No new equity awards may be granted under the 2011 Plan.

On May 11, 2015, 940,112 shares were reserved for issuance under the Company's 2014 Equity Incentive Plan ("2014 Plan"), including 14,006 shares from the 2011 Plan. On January 1, 2016, an additional 273,769 shares were reserved for issuance under the 2014 Plan in accordance with the automatic annual share increase allowed for in the 2014 Plan. As of December 31, 2016, there were 96,008 shares available for issuance under the 2014 Plan.

The Company's Board of Directors determines the option exercise price and grant date for all awards granted. The exercise price of options granted is generally equal to the estimated fair value of the Company's common stock on the date of grant. All options granted have a ten-year term. The vesting period of options and RSUs is established by the Board of Directors but typically ranges between two and four years.

The following table summarizes stock option activity during the two-year period ended December 31, 2016:

| | Number of Shares | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Balance at January 1, 2015 | 595,577 | $ 3.71 | 7.8 | $ - |
| Granted | 171,408 | 6.11 | | |
| Exercised | (13,960) | 2.5 | | $ 86,070 |
| Forfeited | (16,380) | 8.57 | | |
| Balance at December 31, 2015 | 736,645 | $ 4.18 | 7.5 | $ 947,794 |
| Granted | 563,400 | 2.46 | | |
| Exercised | (11,093) | 2.15 | | $ 2,126 |
| Forfeited | (70,754) | 4.60 | | |
| Expired/Cancelled | (56,493) | 3.97 | | |
| Balance at December 31, 2016 | 1,161,705 | $ 3.35 | 7.7 | $ 36,887 |
| Vested and expected to vest at December 31, 2016 | 1,087,266 | $ 3.36 | 7.6 | $ 36,465 |
| Exercisable at December 31, 2015 | 410,649 | $ 3.55 | 6.3 | $ 641,115 |
| Exercisable at December 31, 2016 | 593,670 | $ 3.46 | 6.4 | $ 28,822 |

The weighted-average fair value of stock options granted was $1.59 and $3.61 for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, total unrecognized compensation cost related to stock option awards was approximately $932,153, which is expected to be recognized over approximately 2.3 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 $13,500 for the year ended December 31, 2016.

The fair value of each stock option granted has been determined using the Black-Scholes option pricing model. The material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted for the periods presented were as follows:

| | 2016 | 2015 |
|---|---|---|
| Fair value of common stock | $ 1.98 - 2.88 | $ 4.88 - 14.64 |
| Risk-free interest rate | 1.13% - 2.08% | 1.36% - 2.22% |
| Expected volatility | 59.9% - 93.7% | 60.5% - 75.0% |
| Expected term | 4.8 to 6.2 years | 5.0 to 10 years |
| Expected dividend yield | —% | —% |

- *Expected stock-price volatility*. The expected volatility assumption is derived from the volatility of the Company's common stock in recent periods, as well as that of publicly traded industry competitors, over a period approximately equal to the expected term.
- *Risk-free interest rate*. The risk-free interest rate assumption is based on observed interest rates on the date of grant with maturities approximately equal to the expected term.
- *Expected term*. The expected term represents the period that the stock-based awards are expected to be outstanding. The Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- *Expected dividend yield*. The expected dividend is assumed to be zero as the Company has never paid dividends and does not anticipate paying any dividends on its common stock.

In addition to the assumptions used in the Black-Scholes option-pricing model, the Company also estimates a forfeiture rate to calculate the stock-based compensation for the Company's stock option awards. The Company will continue to use judgment in

evaluating the expected volatility, expected terms and forfeiture rates utilized for the Company's stock-based compensation calculations on a prospective basis.

The following table summarizes RSU award activity during the two-year period ended December 31, 2016:

| | Restricted Stock Units (RSU) | Weighted-Average Grant Date Fair Value Per Share |
|---|---|---|
| Balance at January 1, 2015 | $ — | $ — |
| Granted | 27,500 | 5.45 |
| Vested | — | — |
| Forfeited | — | — |
| Balance at December 31, 2015 | 27,500 | $ 5.45 |
| Granted | 389,761 | 2.43 |
| Vested | (36,762) | 2.90 |
| Forfeited | (25,000) | 2.46 |
| Balance at December 31, 2016 | 355,499 | $ 2.41 |
| Vested and expected to vest at December 31, 2016 | 342,879 | $ 2.42 |

The weighted-average fair value of RSUs granted was $2.43 and $5.45 for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, total unrecognized compensation cost related to RSU awards was approximately $549,744, which is expected to be recognized over approximately 9-months, primarily relating to 353,000 RSUs granted in 2016 that vest 50% on February 27, 2017 and 50% on August 28, 2017, and will be issued upon grantee satisfaction of minimum statutory employee tax withholding liabilities relating to these vested shares.

**Stock Purchase Plan**

In December 2015, the Board of Directors adopted a Stock Purchase Plan (the "Purchase Plan") which allows directors, any individual deemed by the Board of Directors to be an officer for purposes of Section 16 of the Exchange Act, and anyone designated by the Board of Directors as eligible to participate in the Purchase Plan to purchase shares of the Company's common stock from the Company at fair market value. The aggregate number of shares of common stock that may be issued under the Purchase Plan shall not exceed 250,000 shares of common stock, and a maximum of 7,500 shares of common stock may be purchased by any one participant on any one purchase date. The Board of Directors or an authorized committee must review and approve each individual request to purchase common stock under the Purchase Plan. No common stock was sold by the Company under the Purchase Plan for the year ended December 31, 2016. Cash received from the sale of common stock by the Company to eligible participants for the year ended December 31, 2015 was $20,000 which resulted in the sale of 4,184 shares of the Company's common stock at fair market value.

**2014 Employee Stock Purchase Plan**

In April 2015, the Company's stockholders approved the 2014 Employee Stock Purchase Plan, which became effective in May 2015. Initially, the ESPP authorized the issuance of up to 110,820 shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of the Company's designated affiliates. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year, from January 1, 2016 to January 1, 2024 by the least of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (ii) 195,000 shares, or (iii) a number determined by the Company's board of directors that is less than (i) and (ii). 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 is the lesser of: (i) 85% of the fair market value of a share of the Company's common stock on the first day of an offering or (ii) 85% of the fair market value of the Company's common stock at the applicable purchase date.

During the year ended December 31, 2016, employees purchased 39,984 shares at $1.83 per share and 39,978 shares at $2.54 per share at the end of each of the 6-month purchase periods that occurred under the plan. As of December 31, 2016, approximately 99,300 shares of the Company's common stock were reserved for future issuance under the ESPP. The first offering under the ESPP began January 1, 2016. As such, no shares of common stock were issued under the ESPP during the year ended December 31, 2015.

The Company recognizes ESPP expense based on the fair value of the ESPP stock purchase rights, estimated for each 6-month purchase period using the Black-Scholes option pricing model. The model requires the company to make subjective assumptions,

including expected stock price volatility, risk free rate of return and estimated life. The fair value of equity-based awards is amortized straight-line over the vesting period of the award. Stock-based compensation expense relating to the ESPP was $98,544 and $0 for the years ended December 31, 2016 and 2015, respectively.

The material factors incorporated in the Black-Scholes model in estimating the fair value of the ESPP awards for the periods presented were as follows:

| | 2016 |
|---|---|
| Fair value of common stock | $ 3.03 - 4.09 |
| Risk-free interest rate | 0.41% - 0.48% |
| Expected volatility | 70.0% |
| Expected term | 0.5 years |
| Expected dividend yield | —% |

- *Fair value of common stock*. Estimated as the price of the Company's common stock on the first day of each offering period.
- *Expected stock-price volatility*. The expected volatility assumption is derived from the average volatility of the Company's common stock in recent periods, as well as that of publicly traded industry competitors, over a period approximately equal to the expected term.
- *Risk-free interest rate*. The risk-free interest rate assumption is based on observed interest rates on the first day of the purchase period with maturities approximately equal to the expected term.
- *Expected term.* The expected term represents the length of a purchase period under the ESPP.
- *Expected dividend yield*. The expected dividend is assumed to be zero as the Company has never paid dividends and does not anticipate paying any dividends on its common stock.

**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.

**Employment Agreements**

The Company has entered into employment agreements or other arrangements with certain named executive officers, which provides 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 agreement.

**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 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 receive lessor approval for and establish lessee oversight of leasehold improvements by the Company (lessee) and the lessor, respectively, which improvements expanded and improved the Company's existing research, development, operations and administration office facilities. The lease amendments included an increase of $804,000 in total monthly rent over the remaining term of the leases. The landlord constructed certain of the 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 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 annual minimum facility lease payments before common area maintenance charges as of December 31, 2016 are as follows:

| | |
|---|---|
| 2017 | $ 510,125 |
| 2018 | 512,533 |
| 2019 | 514,977 |
| 2020 | 517,457 |
| 2021 | 43,139 |
| | $ 2,098,231 |

Rent expense, including common area maintenance costs for the Company's facilities leases was $561,293, including $130,167 of depreciation for capitalized leasehold improvements for the year ended December 31, 2016. Rent expense, including common area maintenance costs for the Company's facility leases was $443,085 for the year ended December 31, 2015.

As of December 31, 2016, the Company also has capital lease commitments consisting of approximately $123,500 under leases for computer equipment varying in length from 36-48 months and an equipment financing arrangement of approximately $28,500 with a vendor that expires in December 2017 that have not been included in the minimum lease payments schedule above.

**Product Warranty**

The following is a summary of the Company's general product warranty liability, which is included in accrued liabilities in the accompanying balance sheets for the year ended December 31, 2016:

| | Years Ended December 31, 2016 | 2015 |
|---|---|---|
| Beginning balance | $ 20,213 | $ — |
| Cost of warranty claims | (71,404) | (545) |
| Warranty accrual | 101,617 | 20,758 |
| Ending balance | $ 50,426 | $ 20,213 |

Prior to the third quarter of 2015, no warranty reserves were recorded by the Company.

**Defined Contribution Plan**

In January 2003, the Company established a defined contribution plan ("401(k) Plan") under Internal Revenue Code section 401(k). All employees upon hire who are over the age of 21 are eligible for participation in the 401(k) Plan. The Company may make discretionary contributions to the 401(k) Plan, but has not done so during the years ended December 31, 2016 and 2015.

**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. If the tax position is not more likely than not to be sustained in a court of last resort, 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 December 31, 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 December 31, 2016 and 2015, respectively, and has not recognized interest or penalties during the years ended December 31, 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 components of income tax expense are as follows:

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Current: | | |
| Federal | $ — | $ — |
| State | 10,118 | 10,189 |
| Total current income tax expense | $ 10,118 | $ 10,189 |
| | | |
| Deferred: | | |
| Federal | $ — | $ — |
| State | — | — |
| Total deferred income tax expense | $ — | $ — |
| Total income tax expense | $ 10,118 | $ 10,189 |

The Company's actual income tax expense for the years 2016 and 2015 differ from the expected amount computed by applying the statutory federal income tax rate of 34% to loss before income taxes as follows:

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Computed tax (benefit) at 34% | $ (8,850,007) | $ (7,271,785) |
| State taxes, net of federal benefit | (462,609) | (918,079) |
| Stock-based compensation | 210,367 | 102,699 |
| Expiring state net operating loss ("NOL") carryforwards | 94,962 | (20,086) |
| Return to provision | 248,263 | (27,934) |
| Other | 25,718 | 44,679 |
| Research and development tax credit - state | (453,071) | (300,213) |
| Research and development tax credit - federal | (341,785) | (342,681) |
| Change in valuation reserve | 9,538,280 | 8,743,589 |
| | $ 10,118 | $ 10,189 |

Deferred tax assets and liabilities comprise the following:

| | Years Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 37,114,445 | $ 28,795,562 |
| Research and development credits | 2,132,050 | 1,435,314 |
| Deferred revenue | 177,683 | 17,396 |
| Inventory reserve | 99,583 | 104,182 |
| Fixed assets and intangibles | 193,833 | 50,128 |
| Change in fair value of warrant liability | — | 111,993 |
| Accrued NuvoGen liability | 3,176,449 | 3,282,756 |
| Capitalized research and development | — | 27,583 |
| Accrued expense | 351,505 | — |
| Other | 233,438 | 115,792 |
| | 43,478,986 | 33,940,706 |
| Valuation allowance | (43,478,986) | (33,940,706) |
| Deferred tax asset, net | $ — | $ — |

As of December 31, 2016, the Company has estimated federal and state NOL carryforwards of approximately $102,162,333 and $61,744,268 for federal and state income tax purposes, respectively. The Company's federal NOLs are scheduled to expire from 2021 through 2036. The Company's state NOLs are scheduled to expire from 2027 through 2036. The Company's federal and state tax credit carryforwards begin expiring in 2021 and 2017, respectively. The Company's federal NOL carryforwards have the following expiration dates:

| | Year of Expiration | 2016 Bonus Amount |
|---|---|---|
| Federal NOL carryforwards | | |
| | 2021 | $ 211,806 |
| | 2023 | 1,635,651 |
| | 2024 | 1,217,290 |
| | 2025 | 1,409,498 |
| | 2026 | 1,175,594 |
| | 2027 | 1,676,458 |
| | 2028 | 3,037,785 |
| | 2029 | 3,753,314 |
| | 2030 | 623,235 |
| | 2031 | 5,435,312 |
| | 2032 | 10,913,787 |
| | 2033 | 12,095,966 |
| | 2034 | 14,190,409 |
| | 2035 | 21,079,240 |
| | 2036 | 23,706,988 |
| | | $ 102,162,333 |

For financial reporting purposes, valuation allowances of $43,478,986 and $33,940,706 at December 31, 2016 and 2015, respectively, have been established to offset deferred tax assets relating mainly to NOLs and research and development credits. The increase in the valuation allowance of $9,538,280 for the year ended December 31, 2016 was due primarily to increased operating losses. 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 than not to realize the tax benefit. A preliminary analysis of past and subsequent equity offerings by the Company, and other transactions that have an impact on the Company's ownership structure, concluded that the Company may have experienced one or more ownership changes under Sections 382 and 383 of the Internal Revenue Code or IRC. Provisions of the IRC place special limitations on the usage of net operating losses and credits following an ownership change. Such limitations may limit or eliminate the potential future tax benefit to be realized by the Company from its accumulated NOLs and research and development credits.

The Company files income tax returns in the United States, Arizona, California, Texas and various other state jurisdictions, with varying statutes of limitations. As of December 31, 2016, the earliest year subject to examination is 2013 for US federal tax purposes.

The earliest year subject to examination is 2012 for Arizona, California and Texas, and 2009 for the remaining state jurisdictions. However, the Company's net operating loss carryforwards for periods ending December 31, 2001 and thereafter remain subject to examination by the United States and certain states.

**Note 16. Related-Party Transactions**

**Merck Non-Exclusive License Agreement**

In June 2012, the Company entered into a non-exclusive license agreement with Merck Sharp & Dohme Cor. ("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. Merck is an affiliate of Merck Capital Ventures, LLC, which had a 9.9% and 11.1% beneficial ownership in the Company's common stock as of December 31, 2016 and 2015, respectively. A member of the Company's Board of Directors, who resigned in May 2015, was an affiliate of Merck. 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.

**QIAGEN Agreement**

In November 2016, the Company entered a Master Assay Development, Commercialization and Manufacturing Agreement ("Governing Agreement") with QIAGEN Manchester Limited ("QML"), a wholly owned subsidiary of QIAGEN N.V. The Governing Agreement creates a framework for QMS and the Company to combine their technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays. Under the Governing Agreement, the parties will jointly seek companion diagnostic programs with biopharmaceutical companies, QML will contract with interested biopharmaceutical companies for specified projects (each a "Project"), and QML and the Company will enter into a statement of work under the Governing Agreement, which sets forth the rights and obligations of QML and the Company with respect to each Project.

The parties' relationship under the Governing Agreement is exclusive in the oncology field. Such exclusivity in the oncology field may be lost and become non-exclusive if certain performance targets are not met. Projects may be undertaken in non-oncology fields at each party's discretion on a non-exclusive basis.

QML and the Company will share net profits under each statement of work, based on whether development of particular assays under a statement of work are primarily based on HTG or QML intellectual property. Each statement of work will provide additional financial terms for the corresponding Project, which terms will depend on the respective development and/or commercialization activities of the parties.

The Governing Agreement will continue for a five-year term. However, either party may terminate the agreement upon (i) the other party's uncured material breach, bankruptcy or insolvency, (ii) specified events affecting all statements of work, or (iii) a change of control by either party. In the event a party terminates the Governing Agreement for its own change of control, a $2.0 million termination payment will be payable to the non-terminating party.

Pursuant to a stock purchase agreement, entered concurrent with the Governing Agreement, QIAGEN North American Holdings, Inc. ("QNAH"), another wholly owned subsidiary of QIAGEN N.V., purchased 833,333 shares of the Company's common stock on November 17, 2016 at $2.40 per share, for a total purchase price of $2.0 million. QNAH agreed to purchase up to an additional $2.0 million of the Company's common stock (subject to any applicable limitations under the rules of the NASDAQ Stock Market) upon the sale by the Company of at least $12.0 million of common or preferred stock in a financing transaction that occurs prior to May 16, 2017, or such other mutually agreeable date (a "Qualified Financing"). The price per share payable by QNAH in a second tranche closing will be equal to the price per share at which shares are sold in a Qualified Financing.

The purchase price for the shares of common stock purchased by QNAH in the first tranche closing reflected the parties' agreement as to the fair market value of the shares. However, the portion of the purchase price per share that exceeded the most recently reported closing price of the Company's common stock, or $175,000 in the aggregate, was attributed to the Governing Agreement and recorded as deferred revenue. This deferred revenue is being recognized on a straight-line basis over the Governing Agreement's five-year term. For the year ended December 31, 2016, the Company recognized $4,375 of this consideration as revenue. The price QNAH will pay for the shares of the Company's common stock to be purchased in the second tranche closing, if any, will be determined by the price paid by the other investors in the Qualified Financing, and, as such, is expected to represent fair value. Therefore, no value has been given to this financial instrument in the Company's financial statements as of December 31, 2016.

**Note 17. Subsequent Events**

**Notice of Potential Delisting from The NASDAQ Global Market**

The Company's common stock is currently listed on The NASDAQ Global Market under the symbol "HTGM." On August 15, 2016, the Company received notice from NASDAQ that its 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 the Company's submission to NASDAQ of a plan to regain compliance with the stockholders' equity requirements in September 2016, NASDAQ granted the Company an extension until February 13, 2017 to regain compliance with the stockholders' equity requirement. On February 14, 2017, the Company received a letter (the "Delisting Notice") from NASDAQ stating that the Company did not regain compliance with the stockholders' equity requirement and that, as a result, its common stock would be removed from listing unless it requested on appeal to a NASDAQ Hearings Panel. On February 21, 2017, the Company appealed the delisting determination to a NASDAQ Hearings Panel (the "Panel"), pursuant to the procedures set forth in the NASDAQ Listing Rule 5800 series. The hearing request will stay any delisting action in connection with the Delisting Notice and allow the continued listing of the Company's common stock on The NASDAQ Global Market until the Panel renders a decision. A hearing before the Panel has been scheduled for March 30, 2017.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

**None.**

**Item 9A. 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 December 31, 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 annual report, our disclosure controls and procedures were effective at the reasonable assurance level.

***Management's Report on Internal Control over Financial Reporting.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. 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. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our evaluation of the framework in Internal Control – Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2016.

***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 Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and 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.

**Item 9B. Other Information.**

None.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

**Executive Officers and Directors**

The following table sets forth certain information regarding our current executive officers and directors:

| Name | Age | Position(s) |
|---|---|---|
| ***Executive Officers*** | | |
| Timothy B. Johnson | 55 | President and Chief Executive Officer and Director |
| John L. Lubniewski | 53 | Chief Business Officer |
| Patrick C. Roche, Ph.D. | 64 | Senior Vice President for Research and Development |
| Shaun D. McMeans | 55 | Vice President of Finance & Administration and Chief Financial Officer |
| Debra A. Gordon, Ph.D., J.D. | 57 | Vice President and Chief Legal Counsel |
| ***Non-Employee Directors*** | | |
| Ann F. Hanham, Ph.D. (3) | 64 | Chair of the Board of Directors |
| Harry A. George (1) | 68 | Director |
| Donnie B. Hardison (2) | 66 | Director |
| James T. LaFrance (1)(3) | 58 | Director |
| Lee McCracken (2)(3) | 59 | Director |
| Lewis J. Shuster (1) | 61 | Director |

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and governance committee.

**Executive Officers**

*Timothy (TJ) B. Johnson.* Mr. Johnson has served as our President and Chief Executive Officer and as a member of our board of directors since January 2008. Mr. Johnson joined us from LVC Consulting, a consulting company, where he was a partner from April 2007 to January 2008. Prior to April 2007, Mr. Johnson spent five years in leadership roles at Ventana Medical Systems, Inc. or Ventana, a medical diagnostics company, prior to its acquisition by Roche Holdings, Inc., or Roche. At Ventana, Mr. Johnson held the positions of Senior Vice President, Global Business Services, Senior Vice President, Corporate Development and Operations, and Vice President/General Manager, Operations and Lean Systems. In these roles, Mr. Johnson's responsibilities included product technical support, worldwide marketing, corporate development, strategic planning and manufacturing. Prior to working at Ventana, Mr. Johnson had a 12-year career at Hillenbrand Industries, Inc., a global diversified industrial company, where he held several leadership roles in the corporate offices and in the Hill-Rom Division, including Vice President, Global Marketing, Vice President/General Manager, Hill-Rom AirShields, Vice President, Operations, and Vice President, Continuous Improvement and Strategic Planning. Mr. Johnson spent part of his early career at PricewaterhouseCoopers LLP, a public accounting firm. Mr. Johnson previously served on the board of directors of Kalypto Medical, Inc. and was the Industry co-chair for the Biosciences Leadership Council of Southern Arizona. He earned a B.S. in Business from Indiana University. Our board of directors believes that Mr. Johnson's extensive executive background in general management, strategic planning and managing operations of a diagnostic company and service as our President and Chief Executive Officer qualify him to serve on our board of directors.

*John L. Lubniewski.* Mr. Lubniewski has served as our Chief Business Officer since April 2011. Mr. Lubniewski joined us from Ventana, a medical diagnostics company and member of the Roche Group and global headquarters of Roche Tissue Diagnostics, or RTD, where he served in leadership roles for nine years both before and after the acquisition of Ventana by Roche in March 2008. From August 2010 to April 2011, Mr. Lubniewski was Senior Vice President and Lifecycle Leader, Advanced Staining Platforms at Ventana. From January 2008 to August 2010, Mr. Lubniewski served as Senior Vice President and Lifecycle Leader, Clinical Assays at RTD, with responsibility for three lifecycle teams, technical marketing and medical marketing and global accountability for all RTD clinical assay products. Prior to the Roche acquisition of Ventana, Mr. Lubniewski served at Ventana as Senior Vice President, Advanced Staining Business Unit, Vice President Worldwide Marketing and Translational Diagnostic Business Unit, and General Manager, Research Products. In these roles, Mr. Lubniewski was responsible for a variety of assay and platform development and commercialization efforts. Prior to Ventana, Mr. Lubniewski worked for over ten years at Corning, Inc., a manufacturing company, in a variety of divisional, sector and corporate sales and marketing roles. Mr. Lubniewski earned a B.S. in Chemical Engineering from Clarkson University.

*Patrick (Pat) C. Roche, Ph.D.* Dr. Roche has served as our Senior Vice President for Research and Product Development since April 2014. Dr. Roche joined us from Ventana, a medical diagnostics company and member of the Roche Group and global headquarters of RTD, where he worked for 12 years and held a number of positions of increasing responsibility, including Vice President, Head Biomarker Strategy, Translational Diagnostics, from August 2009 to April 2014, and Vice President, Assay Development and Clinical Studies, from March 2007 to July 2009. In these roles, Dr. Roche was responsible for interfacing with biopharmaceutical partners in their development of targeted cancer therapeutics and facilitating the transition of biomarkers into companion diagnostics and for leading reagent product development and launching over 30 in vitro diagnostic products, including the FDA-approved c-kit and HER2 tests. Prior to working at Ventana, Dr. Roche was at the Mayo Clinic Rochester, a medical research group, where he served as Director of the Immunohistochemistry Laboratory and as Associate Professor of Laboratory Medicine and Pathology. Dr. Roche has co-authored more than 125 peer-reviewed publications and is an inventor on a number of patent filings and two issued U.S. patents. Dr. Roche received a B.S. in Biological Sciences from the University of Southern California, and a Ph.D. in Experimental Pathology from the University of Southern California, School of Medicine.

*Shaun D. McMeans*. Mr. McMeans has served as our Vice President of Finance & Administration and Chief Financial Officer since February 2012. Prior to joining us, Mr. McMeans was Vice President – Finance of Securaplane Technologies, Inc., a product supply company and division of Meggitt PLC, an aerospace, defense and energy conglomerate, from May 2011 to February 2012. Mr. McMeans was a financial consultant from February 2008 to April 2011, working both in an individual capacity and as a partner for Tatum LLC, a consulting company. Prior to February 2008, Mr. McMeans was Chief Financial Officer for The Long Companies, a full service residential and commercial real estate division of Berkshire Hathaway, Inc. Mr. McMeans also worked for over five years at LXU Healthcare, Inc., a manufacturer and distributor of specialty surgical equipment, as Controller and then Chief Financial and Operating Officer. In his early career, Mr. McMeans worked in roles of increasing responsibility, including Director of Finance, for Burnham Holdings, Inc., formerly Burnham Corporation, a manufacturer and distributor of residential and commercial hydronic heating equipment. Mr. McMeans received his B.S. in Accounting from The Pennsylvania State University.

*Debra (Deb) A. Gordon, Ph.D., J.D.* Dr. Gordon has served as our Vice President and Chief Legal Counsel since June 2011. Prior to joining us, Dr. Gordon was General Counsel and Head, Patent Legal at Ventana, a medical diagnostics company and a member of the Roche Group and the global headquarters for RTD, from October 2008 to June 2011. Dr. Gordon was promoted to leadership of the Ventana legal function after serving at Ventana from February 2007 as a patent attorney supporting the assay development functions. For nearly ten years preceding Dr. Gordon's in-house legal experiences, Dr. Gordon practiced as a business transactional attorney at the law firms Lewis and Roca LLP (now, Lewis Roca Rothgerber Christie LLP) and Perkins Coie LLP, and as an intellectual property attorney at the law firm Klarquist Sparkman LLP. Prior to law school, Dr. Gordon completed post-doctoral fellowships at Brandeis University and the University of Arizona. Dr. Gordon is an author on 13 peer-reviewed scientific publications and an inventor on two patent filings. Dr. Gordon received a B.S. in Biology and Chemistry and a M.S. in Chemistry from Western Washington University, a Ph.D. in Physiology from the University of Arizona, College of Medicine, and a J.D. with honors from the University of Arizona, James E. Rogers College of Law.

**Non-Employee Directors**

*Ann F. Hanham Ph.D*. Dr. Hanham has served on our board of directors since August 2016, and as the chair of our board of directors since March 2017. Since March 2017, Dr. Hanham has provided independent management consulting as a sole proprietor. Previously, she was the founding and managing partner of BAR Capital LLC, an investment company, a position she has held from December 2013 to March 2017. From February 2000 to November 2013, Dr. Hanham was the Managing Director and General Partner of Burrill and Company, a life science investment company. Prior to that, Dr. Hanham held positions of increasing responsibility in product development, medical affairs, and clinical and regulatory affairs at various companies, including InterMune Inc., Otsuka America Pharmaceuticals, Inc., or Otsuka, Celtrix Pharmaceuticals, Inc., or Celtrix, and Becton Dickinson and Company, or BD. InterMune, Otsuka and Celtrix are, or prior to respective acquisitions, were clinical-stage biopharmaceutical companies, and BD is a life sciences discovery and diagnostics company. Dr. Hanham currently serves on the board of directors of Endocyte, Inc. (NASDAQ: ECYT) and SCYNEXIS (NASDAQ: SCYX). Dr. Hanham received her B.Sc. degree from the University of Toronto, Canada; her M.Sc. degree, in biology, from Simon Fraser University, Canada; and her Ph.D. degree, in biology, from the University of British Columbia, Canada. Our board of directors believes that Ms. Hanham's extensive industry and executive experience, and her experience serving on the board of directors of other public companies qualifies her to serve as the chair of our board of directors.

*Harry A. George*. Mr. George has served on our board of directors since 2002 and served as the chair of our board of directors from December 2007 until September 2013. Mr. George co-founded Solstice Capital, a venture capital firm, in 1995 and serves as its managing general partner. Mr. George has served as a member of the board of directors of a number of private and public companies and is currently serving on the boards of directors of Calimmune, Inc., Tempronics, Inc., Medipacs, Inc., Post.Bid.Ship, Inc., AdiCyte, Inc. and Sharklet. Mr. George is an advisor to Tech Launch Arizona and a board member of the University Venture Fund, Catapult. Additionally, Mr. George is a member of the Southern Arizona Leadership Council and serves on its board of directors and has also

served on the boards of directors of Bio5 Institute, the Arizona-Sonora Desert Museum, the Tucson Museum of Art, and the Pima County Bond Advisory Committee. Prior to 1995, Mr. George was co-founder, Director, and Vice-President of Finance for Interleaf Inc., a software products company. Prior to his time at Interleaf, Mr. George was co-founder, Director and Vice President of Finance of Kurzweil Computer Products, Inc., a computer products company, which subsequently was purchased by Xerox Imaging Systems. Mr. George received an A.B. from Bowdoin College and, in 2012, received an Honorary Doctorate of Science from the University of Arizona. Also in 2012, the Arizona BioIndustry Association conferred upon Mr. George the John McGarrity Bioscience Leader of the Year Award. Our board of directors believes Mr. George's detailed knowledge of our company and long tenure with us, together with his more than 40 years of experience serving as founder, operating officer, or investor with successful rapid growth technology-related companies qualify him to serve on our board of directors.

*Donnie M. Hardison*. Mr. Hardison has served on our board of directors since May 2016. In April 2016, he founded and serves as the sole proprietor of DMH Consulting, a management consulting firm. Between April 2010 and March 2016, Mr. Hardison was the President and Chief Executive Officer of Good Start Genetics, a medical device company. For more than 20 years prior to that, Mr. Hardison held a number of executive and senior management positions at companies including Laboratory Corporation of America, or LabCorp, a clinical laboratory company, Exact Sciences Corporation, a molecular diagnostics company, OnTarget, Inc., a sales and marketing consulting company, Quest Diagnostics Inc., a clinical laboratory company, SmithKline Beecham Corporation, a pharmaceutical company, and others. He currently serves on the board of directors of Seventh Sense Biosystems, a privately held medical technology company, and has served on the board of directors of several other private companies, including Good Start Genetics. He also served on the board of directors of Exact Science Corporation (NASDAQ: EXAS) from May 2000, through its initial public offering in February 2001, until August 2007. Mr. Hardison received his Bachelor of Arts degree, in political science, from the University of North Carolina, Chapel Hill. Our board of directors believes that Mr. Hardison's broad private and public company background, his extensive executive and industry experience, his experience with newly emerging and well-established companies, and his extensive commercial and operational experience qualify him to serve on our Board of Directors.

*James (Jim) T. LaFrance*. Mr. LaFrance has served on our board of directors since December 2015. Mr. LaFrance has almost thirty years of diagnostic industry experience working since January 2015 as a sales, marketing, strategy development and commercial operational management consultant for LaFrance Consulting LLC, a firm he founded. He served as interim Chief Executive Officer of Vermillion, Inc. (NASDAQ: VRML), a bioanalytics service provider, from April 2014 to December 2014, where he also has served as chairman of the board of directors since December 2013. From November 2013 to March 2014, he served as a consultant in the medical diagnostics sector for his firm, LaFrance Consulting LLC. Prior to that, he was head of digital pathology and Chief Executive Officer of Omnyx, LLC for GE Healthcare from January 2012 to October 2013. From August 2009 to December 2011, he further served as a consultant in the medical diagnostics for LaFrance Consulting LLC. For eight years earlier in his career, Mr. LaFrance held a series of commercial, strategic marketing and business development leadership roles at Ventana Medical Systems (now Roche Tissue Diagnostics), or Ventana, including general management of the North American and international commercial operations. Prior to working for Ventana, Mr. LaFrance served in leadership roles in strategic marketing and business development at Bayer Diagnostics. He earned a Bachelor of Arts degree in Economics from the University of Connecticut and holds a Master's in Business Administration from the University of Notre Dame. Our board of directors believes that Mr. LaFrance's extensive industry and executive experience, and his experience serving on the board of directors of another public company qualify him to serve on our board of directors.

*Lee McCracken*. Mr. McCracken has served on our board of directors since October 2015. Mr. McCracken currently is Chairman of Global Medical and Research Technologies, a company focused on solutions for organ transplantation and regenerative medicine therapies, a position he has held since May 2016. From April 2014 to May 2016, Mr. McCracken was Chief Executive Officer of Gensignia Life Sciences, Inc. Prior to that, from April 2013 to March 2014, he served as a strategic and restructuring consultant in the regenerative medicine and diagnostic sectors in his firm, McCracken Consulting. From October 2012 to March 2013, Mr. McCracken served as the President and Chief Executive Officer of Pathwork Diagnostics, Inc., a molecular diagnostics company. From January 2012 to September 2012, he was a strategic consultant in the molecular diagnostics sector in his firm, McCracken Consulting. Beginning in 2004 through December 2011, he was the Corporate Head of Business Development and a consultant for Prometheus Laboratories Inc., a pharmaceutical and medical diagnostics company. Earlier in his career, Mr. McCracken held a number of executive positions or roles with significant responsibility at several biotechnology and therapeutics companies, including GenStar Therapeutics Corporation, CombiChem Inc., and Allergan Inc., as well as at the investment companies, 3i Capital and Union Venture. Mr. McCracken received his M.B.A. from the Anderson School of Management at the University of California, Los Angeles, his Master of Computer Science (MCS) from the University of Dayton, and his B.S. in Commerce from Santa Clara University. He currently serves as a director of several private companies including Global Medical and Research Technologies, Inc. Our board of directors believes Mr. McCracken's extensive executive and industry experience and his broad knowledge of molecular diagnostics qualify him to serve on our board of directors.

*Lewis (Lew) J. Shuster*. Mr. Shuster has served on our board of directors since March 2014. In 2002, Mr. Shuster founded Shuster Capital, a strategic and operating advisor to and angel investor in life science companies, and has served as its chief executive

officer since that time. From June 2003 to November 2007, Mr. Shuster served as chief executive officer of Kemia, Inc., a drug discovery and development company. From February 2000 to December 2001, Mr. Shuster held various operating executive positions at Invitrogen Corporation, a biotechnology company that merged with Applied Biosystems Inc. and became Life Technologies Corporation. Between 1994 and 1999, Mr. Shuster served as chief financial officer and other executive positions at Pharmacopeia, Inc., a drug discovery product and service company. Mr. Shuster joined Human Genome Sciences, Inc. as its first employee in September 1992 and served as its executive vice president, operations and finance until 1994. From June 2011 until December 2016, Mr. Shuster served as a member of the board of directors of Response Biomedical Corporation. From April 2010 to March 2013, Mr. Shuster served as a director of Complete Genomics, Inc., a life science company, and, from April 2011 to March 2016, as a director of Mast Therapeutics, Inc., a biopharmaceutical company. Mr. Shuster received a B.A. in Economics from Swarthmore College and an M.B.A. from Stanford University. Our board of directors believes that Mr. Shuster's extensive executive background in strategic planning and managing rapid operations growth for multiple public and private life science companies qualify him to serve on our board of directors.

**Board Composition**

Our business and affairs are organized under the direction of our board of directors, which consists of eight members as of December 31, 2016. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors other than Mr. Johnson are independent directors, as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules. The NASDAQ independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by NASDAQ rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

In accordance with the terms of our amended and restated certificate of incorporation, our board of directors is divided into three classes, as follows:

- Class I, which consists of Mr. McCracken and Mr. LaFrance, whose terms will expire at our annual meeting of stockholders to be held in 2019;
- Class II, which consists of Mr. George and Mr. Hardison, whose terms will expire at our annual meeting of stockholders to be held in 2017; and
- Class III, which consists of Mr. Johnson, Mr. Shuster and Dr. Hanham, whose terms will expire at our annual meeting of stockholders to be held in 2018.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

**Board Leadership Structure**

Our board of directors is currently chaired by Dr. Hanham. As a general policy, our board of directors believes that separation of the positions of chair and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Johnson serves as the President and Chief Executive Officer while Dr. Hanham serves as the chair of our board of directors but is not an officer. We expect the positions of chair of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

**Role of the Board in Risk Oversight**

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Oversight by the audit committee includes direct communication with our external auditors. Our nominating and governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

**Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and governance committee.

***Audit Committee***

Our audit committee consists of Mr. Shuster, Mr. George and Mr. LaFrance. Mr. Shuster serves as the chair of our audit committee. Our board of directors has determined that each of the members of our audit committee satisfies the NASDAQ Stock Market and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;

- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that each member of the audit committee meets the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Stock Market. It has also determined that Mr. Shuster qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the NASDAQ Listing Rules. In making this determination, our board of directors has considered Mr. Shuster's formal education and experience in financial and executive roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and the NASDAQ Stock Market.

***Compensation Committee***

Our compensation committee consists of Mr. McCracken and Mr. Hardison. Mr. McCracken serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and satisfies the NASDAQ Stock Market independence requirements. None of these individuals has ever been an executive officer or employee of ours. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and recommending to our board of directors the compensation and other terms of employment of our executive officers;
- reviewing and recommending to our board of directors the performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies for allocating between long-term and currently paid out compensation, between cash and non-cash compensation and the factors used in deciding between the various forms of compensation;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- establishing elements of corporate performance for purposes of increasing or decreasing compensation;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing regional and industry-wide compensation practices and trends to assess the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing the adequacy of its charter on a periodic basis;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC, if applicable;

- preparing the report that the SEC requires in our annual proxy statement, if applicable; and
- reviewing and assessing on an annual basis the performance of the compensation committee.

The compensation committee operates under a written charter that satisfies the applicable standards of the SEC and the NASDAQ Stock Market.

None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

***Nominating and Governance Committee***

Dr. Hanham was appointed by our board of directors to be the chair of our nominating and governance committee in August 2016 and Mr. McCracken and Mr. LaFrance are members of the committee. Our board of directors has determined that each of the members of this committee satisfies the NASDAQ Stock Market independence requirements. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- assist the chair of our board of directors or lead independent director in developing effective board of directors meeting practices and procedures;
- oversee and review the processes and procedures used by us to provide information to our board of directors and its committees;
- assist the members of our compensation committee, as requested, in determining the compensation paid to non-employee directors for their service on our board of directors and its committees and recommend any changes considered appropriate to our full board of directors for approval;
- periodically review with our Chief Executive Officer the plans for succession to the offices of our Chief Executive Officer and other key executive officers and make recommendations to our board of directors with respect to the selection of appropriate individuals to succeed those positions;
- reviewing the adequacy of its charter on an annual basis; and
- annually evaluating the performance of the nominating and governance committee.

The nominating and governance committee operates under a written charter, which the nominating and governance committee reviews and evaluates at least annually.

The nominating and governance committee will consider qualified director candidates recommended by stockholders in compliance with our procedures and subject to applicable inquiries. The nominating and governance committee's evaluation of candidates recommended by stockholders does not differ materially from its evaluation of candidates recommended from other sources. Any stockholder may recommend nominees for director by writing to Dr. Ann F. Hanham, Ph.D., Chair of the Nominating and Governance Committee of the Board of Directors, HTG Molecular Diagnostics, Inc., 3430 E. Global Loop, Tucson, Arizona 85706, giving the name and address of the stockholder on whose behalf the submission is made, the number of Company shares that are owned beneficially by such stockholder as of the date of the submission, the full name of the proposed candidate, a description of the proposed candidate's business experience for at least the previous five years, complete biographical information for the proposed

candidate and a description of the proposed candidate's qualifications as a director. All of these communications will be reviewed by our nominating and governance committee, for further review and consideration in accordance with this policy.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Under Section 16(a) of the Exchange Act, directors, officers and beneficial owners of 10% or more of our common stock are required to file with the SEC on a timely basis initial reports of beneficial ownership and reports of changes regarding their beneficial ownership of our common stock. Officers, directors and 10% beneficial owners are required by SEC regulations to furnish us with copies of all Section 16(a) forms that they file.

Based solely on our review of the copies of such forms received and the written representations from certain reporting persons, we have determined that no officer, director or 10% beneficial owner known to us was delinquent with respect to their reporting obligations as set forth in Section 16(a) of the Exchange Act during the fiscal year ended December 31, 2016.

**Limitation on Liability and Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation and bylaws limits our directors' and officers' liability to the fullest extent permitted under Delaware corporate law. Delaware corporate law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any transaction from which the director derives an improper personal benefit;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (unlawful payment of dividends or redemption of shares); or
- for any breach of a director's duty of loyalty to the corporation or its stockholders.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors or officers, then the liability of our directors or officers shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Delaware law and our amended and restated bylaws provide that we will, in certain situations, indemnify any person made or threatened to be made a party to a proceeding by reason of that person's former or present official capacity with us against judgments, penalties, fines, settlements and reasonable expenses. Any person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request.

We believe that these provisions in our amended and restated certificate of incorporation and amended bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Stockholder Communications with the Board of Directors**

We have adopted a formal process by which stockholders may communicate with our board of directors or any individual director. Stockholders who wish to communicate with our board of directors or any individual director may do so by sending written communications addressed to our Secretary at 3430 E. Global Loop, Tucson, Arizona, 85706. These communications will be reviewed by our Secretary, who will determine whether the communication is appropriate for presentation to our board of directors or the relevant director. The purpose of this screening is to allow our board of directors to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

**Code of Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at www.htgmolecular.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

**Item 11. Executive Compensation.**

Our named executive officers for the year ended December 31, 2016, which consist of our principal executive officer and our two other most highly compensated executive officers as of December 31, 2016, are as follows:

- Timothy B. Johnson, our President and Chief Executive Officer;
- John L. Lubniewski, our Chief Business Officer; and
- Patrick C. Roche, Ph.D., our Senior Vice President for Research and Development.

**Summary Compensation Table**

| Name and principal position | Year | Salary ($) | Restricted Stock Unit Awards ($) (1) | Option Awards ($) (2) | Non-equity incentive plan compensation ($) (3) | All Other Compensation ($) (4) | Total ($) |
|---|---|---|---|---|---|---|---|
| Timothy B. Johnson | 2016 | 400,000 | 98,400 | 247,800 | — | 328 | 746,528 |
| *President and Chief Executive Officer* | 2015 | 382,952 | 81,750 | — | 120,000 | 647 | 585,349 |
| John L. Lubniewski | 2016 | 299,614 | 49,200 | 82,600 | | 328 | 431,742 |
| *Vice President and Chief Business Officer* | 2015 | 289,604 | 13,625 | — | 70,440 | 647 | 374,316 |
| Patrick C. Roche, Ph.D. | 2016 | 257,250 | 49,200 | 200,600 | — | 328 | 507,378 |
| *Senior Vice President of Research & Development* | 2015 | 246,500 | — | — | 49,200 | 624 | 296,324 |

(1) The dollar amounts in this column represent the aggregate grant date fair value of RSU awards granted in 2016 and 2015, as applicable. For further discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our financial statements included elsewhere in this Annual Report on Form 10-K.

(2) The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2016 and 2015, as applicable. These amounts have been computed in accordance with FASB ASC Topic 718, using the Black-Scholes option pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our financial statements included elsewhere in this Annual Report on Form 10-K.

(3) Amounts shown represent annual performance-based bonuses earned for 2015. The annual performance-based bonuses earned for 2015 were paid in the form of fully vested shares of common stock granted under the 2014 Plan. As of the filing of this Annual Report, the determination of annual performance-based bonuses for 2016 has been deferred. For more information, see below under "—Annual Performance-Based Bonus Opportunity."

(4) Amount shown represents premiums for life, disability and accidental death and dismemberment insurance paid by us on behalf of the named executive officer.

**Annual Base Salary**

The base salary of our named executive officers is generally set forth in each officer's employment letter agreement with us and periodically reviewed and adjusted as necessary by our board of directors, based on the recommendation of the compensation committee of our board of directors. The 2016 base salaries for our named executive officers, which were effective in the second quarter of 2015, were $400,000, $293,500 and $252,000, for Mr. Johnson, Mr. Lubniewski and Dr. Roche, respectively. In March 2016, the base salaries for Mr. Lubniewski and Dr. Roche were increased to $300,837.50 and $258,300, respectively.

**Annual Performance-Based Bonus Opportunity**

In addition to base salaries, our named executive officers are eligible to receive annual performance-based bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is generally based on the extent to which we achieve the corporate goals that our board of directors establishes each year. At the end of the year, our board of directors reviews our performance against each corporate goal and approves the extent to which we achieved each of our corporate goals.

Our board of directors will generally consider each named executive officer's individual contributions towards reaching our annual corporate goals but does not typically establish specific individual goals for our named executive officers. There is no minimum bonus percentage or amount established for the named executive officers and, thus, the bonus amounts vary from year to year based on corporate and individual performance. For 2016, Mr. Johnson was eligible to receive a target bonus of up to 50% of his base salary pursuant to the terms of his employment letter agreement described below. For 2016, Mr. Lubniewski was eligible to receive a target bonus of up to 40% of his base salary pursuant to the terms of his employment letter agreement described below. For 2016, Dr. Roche was eligible to receive a target bonus of up to 40% of his base salary pursuant to the terms of his employment letter agreement described below.

The corporate goals established by our board of directors for 2016 were based upon commercial, research and development, and financial goals. Specific goals included increasing the number of biopharmaceutical company drug-development programs using HTG technology, product development milestone achievement, including new assay development, FDA submission and Project JANUS milestones, and expansion of biopharmaceutical customer relationships through collaboration agreements. The commercial goals were weighted at 30% towards overall corporate goal achievement, the research and development goals were weighted 20% towards overall corporate goal achievement, and the financial goals were weighted 50% towards overall corporate goal achievement. There was no minimum percentage of corporate goals that must be achieved to earn a bonus. No specific individual goals were established for any of our named executive officers for 2016.

In January 2017, for purposes of approving a bonus pool for non-executive officer employees, our board of directors determined that the 2016 corporate goals had been achieved at an aggregate level of 47.5%. However, in view of the Company's financial condition, the determination and payment of bonuses for our executive officers, including our named executive officers, was deferred.

**Equity-Based Incentive Awards**

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. Our board of directors or any authorized committee thereof is responsible for approving equity grants, which include to date, stock options and RSUs. Vesting of the stock option and RSU awards is tied to continuous service with us and serves as an additional retention measure. Our executives generally are awarded an initial stock option grant upon commencement of employment. Additional equity awards may occur periodically to specifically incentivize executives to achieve certain corporate goals or to reward executives for exceptional performance. As of December 31, 2016, our named executive officers have been granted both stock option awards and RSUs.

Prior to the initial public offering, we granted all equity awards pursuant to the 2011 Plan and the 2001 Plan. All equity awards granted since our initial public offering have been granted pursuant to the 2014 Plan, the terms of which are described below under "—Equity Benefit Plans." All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of the grant of such award.

Generally, our stock option awards vest over a four-year period subject to the holder's continuous service to us and may be granted with an early exercise feature. Such early exercise feature allows the holder to exercise and receive unvested shares of our stock, so that the holder may have a greater opportunity for gains on the shares to be taxed at long-term capital gains rates rather than ordinary income rates. From time to time as our board of directors considers appropriate, we may grant stock options or RSUs that vest upon achievement of performance goals.

On August 26, 2016, our board of directors granted Mr. Johnson, Mr. Lubniewski and Dr. Roche RSUs for 40,000, 20,000, and 20,000 shares of our common stock, respectively, which will vest 50% on February 28, 2017 and 50% on August 28, 2017, subject to continued service by each of these individuals through that date. See "—Outstanding Equity Awards at Fiscal Year-End."

**Agreements with Named Executed Officers**

We have entered into letter agreements with each of our named executive officers. The letter agreements generally provide for at-will employment and set forth the named executive officer's initial base salary, eligibility for employee benefits, in some cases, and severance benefits upon a qualifying termination of employment. In addition, each of our named executive officers has executed a form of our standard confidential information and invention assignment agreement. The key terms of the letter agreements with our named executive officers are described below. Any potential payments and benefits due upon a qualifying termination of employment or a change in control are further described below under "– Potential Payments and Benefits upon Termination or Change in Control."

*Employment Letter Agreement with Mr. Johnson.* We entered into an amended and restated letter agreement with Mr. Johnson in December 2014 that replaced his previous letter agreement and became effective at completion of our IPO. The agreement sets forth certain agreed upon terms and conditions of employment. Under the amended and restated letter agreement, Mr. Johnson serves as our President and Chief Executive Officer. Mr. Johnson is entitled to an annual base salary of $400,000, is eligible to receive an annual target performance bonus of up to 50% of his base salary as determined by the board of directors, and certain severance benefits, the terms of which are described below under "—Potential Payments and Benefits upon Termination or Change of Control." Mr. Johnson's base salary and target bonus percentage are subject to modification from time to time in the discretion of our board of directors or any authorized committee thereof.

*Employment Letter Agreement Mr. Lubniewski.* We entered into an amended and restated letter agreement with Mr. Lubniewski in December 2014 that replaced his previous letter agreement and became effective at completion of our IPO. The agreement sets forth certain agreed upon terms and conditions of employment. Under the amended and restated letter agreement, Mr. Lubniewski serves as our Chief Business Officer. Mr. Lubniewski was initially entitled to receive an annual base salary of $293,500, is eligible to receive an annual target performance bonus of up to 40% of his base salary as determined by the board of directors, and certain severance benefits, the terms of which are described below under "—Potential Payments and Benefits upon Termination or Change of Control." Mr. Lubniewski's base salary and target bonus percentage are subject to modification from time to time in the discretion of our board of directors or any authorized committee thereof. Effective March 1, 2016, our board of directors approved an increase to Mr. Lubniewski's annual base salary to $300,837.50.

*Employment Letter Agreement with Dr. Roche.* We entered into an amended and restated letter agreement with Dr. Roche in December 2014 that replaced his previous letter agreement and became effective at completion of our IPO. The agreement sets forth certain agreed upon terms and conditions of employment. Under the amended and restated letter agreement, Dr. Roche serves as our Senior Vice President of Research and Development. Dr. Roche was initially entitled to an annual base salary of $240,000, is eligible to receive an annual target performance bonus of up to 40% of his base salary as determined by the board of directors, and certain severance benefits, the terms of which are described below under "—Potential Payments and Benefits upon Termination or Change of Control." Dr. Roche's base salary and target bonus percentage are subject to modification from time to time in the discretion of our board of directors or any authorized committee thereof. Effective March 1, 2016, our board of directors approved an increase to Dr. Roche's annual base salary to $258,300.

**Potential Payments and Benefits upon Termination or Change of Control**

Under the terms of our named executive officers' amended and restated letter agreements upon the executive's termination without "cause," or resignation for "good reason," each as defined below, including any such termination that occurs in connection with a change of control, each of our named executive officers is eligible to receive continued base salary payments and COBRA premium payments for 12 months for Mr. Johnson and nine months for Mr. Lubniewski and Dr. Roche.

For purposes of the amended and restated letter agreements, "cause" generally means the occurrence of any of the following events, conditions or actions with respect to the executive: (1) conviction of any felony or crime involving fraud or dishonesty; (2) participation in any material fraud, material act of dishonesty or other material act of misconduct against us; (3) willful and habitual neglect of the executive's duties after written notice and opportunity to cure; (4) material violation of any fiduciary duty or duty of loyalty owed to us; (5) breach of any material term of any material contract with us which has a material adverse effect on us; (6) knowing violation of any material company policy which has a material adverse effect on us; or (7) knowing violation of state or federal law in connection with the performance of the executive's job which has a material adverse effect on us.

For purposes of each of the named executive officer's amended and restated letter agreements, "good reason" generally means the following events, conditions or actions taken by us with respect to the executive without cause and without the executive's express

written consent: (1) a material reduction in base salary; (2) a material reduction in the executive's authority, duties or responsibilities; (3) a material reduction in the authority, duties or responsibilities of the supervisor to whom the executive is required to report; or (4) a relocation of the executive's principal place of employment to a place that increases the executive's one-way commute by more than 50 miles.

Each of our named executive officers holds stock options and RSUs under our equity incentive plans that were granted subject to our form of stock option and RSU agreements. A description of the termination and change of control provisions in such equity incentive plans and stock options and RSUs granted thereunder is provided below under "– Equity Benefit Plans" and the specific vesting terms of each named executive officer's stock options and RSUs are described below under "– Outstanding Equity Awards at Fiscal Year-End."

**Outstanding Equity Awards at Fiscal Year-End**

The following table presents information concerning equity awards held by our named executive officers as of December 31, 2016, granted under the 2001 Plan, the 2011 Plan and the 2014 Plan.

| | | | Option Awards | | | | | Stock Awards | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | | Grant Date/Vesting Commencement Date | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($) | Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) | Equity incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) |
| Timothy B. Johnson | (1) | 1/16/2008 | 25,048 | — | — | 6.44 | 1/16/2018 | — | — | — | — |
| | (1) | 10/23/2008 | 14,407 | — | — | 6.44 | 10/23/2018 | — | — | — | — |
| | (1) | 3/01/2009 | 4,655 | — | — | 4.30 | 3/01/2019 | — | — | — | — |
| | (1) | 3/01/2010 | 6,983 | — | — | 4.30 | 3/01/2020 | — | — | — | — |
| | (1) | 4/13/2010 | 675 | — | — | 4.30 | 4/13/2020 | — | — | — | — |
| | (1) | 10/21/2010 | 581 | — | — | 4.30 | 10/21/2020 | — | — | — | — |
| | (1) | 1/20/2011 | 675 | — | — | 4.30 | 1/20/2021 | — | — | — | — |
| | (1) | 4/26/2011 | 29,797 | — | — | 2.15 | 4/26/2021 | — | — | — | — |
| | (1) | 2/01/2013 | 18,328 | — | — | 2.15 | 2/01/2023 | — | — | — | — |
| | (2) | 8/06/2013 | 8,134 | 1,177 | — | 2.15 | 8/06/2023 | — | — | — | — |
| | (2) | 3/20/2014 | 32,448 | 10,819 | — | 2.15 | 3/19/2024 | — | — | — | — |
| | (2) | 12/29/2014 | 5,237 | 4,074 | — | 12.89 | 12/28/2024 | — | — | — | — |
| | (2) | 2/16/2016 | 32,812 | 72,188 | — | 2.36 | 2/15/2026 | — | — | — | — |
| | (3) | 8/26/2016 | — | — | — | — | n/a | 40,000 | $89,600 | — | — |
| John L. Lubniewski | (1) | 4/26/2011 | 13,036 | — | — | 2.15 | 4/26/2021 | — | — | — | — |
| | (1) | 3/08/2012 | 2,793 | — | — | 2.15 | 3/08/2022 | — | — | — | — |
| | (1) | 2/01/2013 | 3,503 | — | — | 2.15 | 2/01/2023 | — | — | — | — |
| | (2) | 8/06/2013 | 11,396 | 1,640 | — | 2.15 | 8/06/2023 | — | — | — | — |
| | (2) | 3/20/2014 | 22,356 | 7,462 | — | 2.15 | 3/20/2024 | — | — | — | — |
| | (2) | 12/29/2014 | 2,096 | 1,628 | — | 12.89 | 12/29/2024 | — | — | — | — |
| | (2) | 2/16/2016 | 10,937 | 24,063 | — | 2.36 | 2/15/2026 | — | — | — | — |
| | (3) | 8/26/2016 | — | — | — | — | n/a | 20,000 | $44,800 | — | — |
| Patrick C. Roche, Ph.D. | (2) | 3/20/2014 | 9,603 | 4,364 | — | 2.15 | 3/20/2024 | — | — | — | — |
| | (2) | 12/29/2014 | 1,313 | 1,014 | — | 12.89 | 12/29/2024 | — | — | — | — |
| | (2) | 2/16/2016 | 26,562 | 58,438 | — | 2.36 | 2/15/2026 | — | — | — | — |
| | (3) | 8/26/16 | — | — | — | — | n/a | 20,000 | $44,800 | — | — |

(1) Fully vested.
(2) Options vest over four years as follows: 1/16 of the outstanding shares vest at the end of each calendar quarter over a period of approximately four years, subject to the individual's continued service with us through each vesting date.
(3) RSUs vest 50% on February 27, 2017 and 50% on August 28, 2017, subject to the individual's continued service with us through each of those dates.

**Equity Benefit Plans**

***2014 Equity Incentive Plan***

Our board of directors adopted the 2014 Plan in December 2014 and our stockholders approved the 2014 Plan in April 2015. The 2014 Plan became effective on May 5, 2015 in connection with our initial public offering.

*Stock Awards*. The 2014 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2014 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

*Share Reserve*. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2014 Plan was the sum of (1) 925,616 shares, plus (2) the number of shares (not to exceed 608,819 shares) (i) reserved for issuance under our 2011 Plan at the time the 2014 Plan became effective, and (ii) any shares subject to outstanding stock options or other stock awards that were granted under our 2011 Plan or 2001 Plan that, on or after the effective date of the 2014 Plan, are forfeited, terminate, expire or are otherwise not issued. Additionally, the number of shares of our common stock reserved for issuance under the 2014 Plan automatically increases on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2024, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued upon the exercise of ISOs under the 2014 Plan is 1,800,000 shares.

No person may be granted stock awards covering more than 200,000 shares of our common stock under the 2014 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 200,000 shares of our common stock or a performance cash award having a maximum value in excess of $2,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code.

If a stock award granted under the 2014 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2014 Plan. In addition, the following types of shares of our common stock under the 2014 Plan may become available for the grant of new stock awards under the 2014 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2014 Plan may be previously unissued shares or reacquired shares bought by us on the open market. As of December 31, 2016, option awards covering an aggregate of 674,309 shares of our common stock have been granted under the 2014 Plan and were outstanding and an additional 355,499 RSU awards have been granted and remain outstanding and unvested.

*Administration*. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2014 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2014 Plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability, vesting schedule and change of control provision applicable to a stock award, if any. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under the 2014 Plan. Subject to the terms of the 2014 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

*Stock Options*. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2014 Plan, provided that the

exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2014 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2014 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

*Tax Limitations on Incentive Stock Options*. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

*Restricted Stock Awards*. Restricted stock awards may be granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

*Restricted Stock Unit Awards*. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. RSUs may be granted in consideration for any form of legal consideration. An RSU award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. RSUs typically vest and underlying shares of common stock are delivered as outlined in the applicable RSU agreements following the grantee's satisfaction of minimum statutory employee tax withholding requirements, where applicable. Employee RSU agreements generally provide that vesting is accelerated only in certain circumstances, that delivery of the underlying shares of common stock is conditioned on the grantee's satisfying certain vesting conditions outlined in the award, and that the grantee's employment continue with the Company through the vesting date. Additionally, dividend equivalents may be credited in respect of shares covered by an RSU award. Except as otherwise provided in the applicable award agreement, RSUs that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Stock Appreciation Rights*. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2014 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2014 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provide otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

*Performance Awards*. The 2014 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation, other non-cash expenses and changes in deferred revenue; (9) total stockholder return; (10) return on equity or average stockholder's equity; (11) return on assets, investment, or capital employed; (12) stock price; (13) margin (including gross margin); (14) income (before or after taxes); (15) operating income; (16) operating income after taxes; (17) pre-tax profit; (18) operating cash flow; (19) sales or revenue targets; (20) increases in revenue or product revenue; (21) expenses and cost reduction goals; (22) improvement in or attainment of working capital levels; (23) economic value added (or an equivalent metric); (24) market share; (25) cash flow; (26) cash flow per share; (27) cash balance; (28) cash burn; (29) cash collections; (30) share price performance; (31) debt reduction; (32) implementation or completion of projects or processes (including, without limitation, clinical study initiation, clinical study enrollment and dates, clinical study results, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, and product supply); (33) stockholders' equity; (34) capital expenditures; (35) debt levels; (36) operating profit or net operating profit; (37) workforce diversity; (38) growth of net income or operating income; (39) billings; (40) bookings; (41) employee retention; (42) initiation of studies by specific dates; (43) budget management; (44) submission to, or approval by, a regulatory body (including, but not limited to the FDA) of an applicable filing or a product; (45) regulatory milestones; (46) progress of internal research or development programs; (47) acquisition of new customers; (48) customer retention and/or repeat order rate; (49) improvements in sample and test processing times; (50) progress of partnered programs; (51) partner satisfaction; (52) timely completion of clinical studies; (53) submission of 510(k)s or pre-market approvals and other regulatory achievements; (54) milestones related to samples received and/or tests or panels run; (55) expansion of sales in additional geographies or markets; (56) research progress, including the development of programs; (57) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); and (58) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally

accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the performance goals and to define the manner of calculating the performance criteria we select to use for such performance period. The performance goals may differ from participant to participant and from award to award.

*Other Stock Awards*. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

*Changes to Capital Structure*. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2014 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, (4) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2014 Plan pursuant to Section 162(m) of the Code) and (5) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions*. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination at or prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2014 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

*Change of Control*. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. For example, certain of our employees may receive an award agreement that provides for vesting acceleration upon the individual's termination without cause or resignation for good reason (including a material reduction in the individual's base salary, duties, responsibilities or authority, or a material relocation of the individual's principal place of employment with us) in connection with a change of control. Under the 2014 Plan, a change of control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (3) a consummated sale, lease or exclusive license or other disposition of all or substantially of our assets; or (4) our stockholders approve a plan of our complete dissolution or liquidation or our complete dissolution or liquidation otherwise occurs.

All options granted under the 2014 Plan to our named executive officers provide that vesting and exercisability of such options will be accelerated in full following a change in control if, immediately prior to or within 12 months after the effective time of such change in control, the optionholder's continuous service terminates due to an involuntary termination without cause or due to a voluntary termination with good reason. Several terms are specifically defined in the 2014 Plan for purposes of this "double-trigger"

provision; in particular, (i) "good reason" is generally defined as (1) a material reduction in the optionholder's annual base salary, except pursuant to a salary reduction program affecting substantially all of our employees that does not disproportionately affect the optionholder; (2) a material reduction in the optionholder's authority, duties or responsibilities; (3) any failure by us to continue any material benefit plan or program in which the optionholder was participating immediately prior to the change in control, or any action by us that would adversely affect the optionholder's participation in or reduce his/her benefits under such benefit plan or program, or deprive him/her of any fringe benefit enjoyed immediately prior to the change in control, unless, taken as a whole, we provide for optionholder participation in comparable benefit plans or programs; (4) a relocation of the optionholder's principal place of employment more than 50 miles; or (5) a material breach by us of any provision of the 2014 Plan or an option agreement under the 2014 Plan or any other material agreement between the optionholder and us concerning the terms and conditions of employment or service with us; and (ii) "cause" is generally defined as the occurrence of any of the following events: (A) the optionholder's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (B) the optionholder's attempted commission of, or participation in, a fraud or act of dishonesty against us; (C) the optionholder's intentional, material violation of any contract or agreement between the optionholder and us or of any statutory duty owed to us; (D) the optionholder's unauthorized use or disclosure of our confidential information or trade secrets; or (E) the optionholder's gross misconduct.

*Amendment and Termination*. Our board of directors has the authority to amend, suspend, or terminate the 2014 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted the 2014 Plan.

***2011 Equity Incentive Plan***

*General*. Our board of directors and our stockholders approved our 2011 Plan in March 2011. The 2011 Plan was subsequently amended by our board of directors and our stockholders, most recently in February 2014. The 2011 Plan is the successor to and continuation of our 2001 Plan. As of December 31, 2016, option awards under the 2011 Plan covering an aggregate of 412,715 shares of our common stock were outstanding. No additional awards will be granted under the 2011 Plan and all outstanding awards granted under the 2011 Plan that are repurchased, forfeited, expire or are cancelled will become available for grant under the 2014 Plan in accordance with its terms. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2011 Plan. Our board of directors may also delegate certain authority to one or more of our officers. The plan administrator has the authority to modify outstanding awards under our 2011 Plan, including the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

*Stock Options.* ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2011 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2011 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2011 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

*Corporate Transactions*. Unless otherwise provided in a stock award agreement or other written agreement between us and a participant, in the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;

- accelerate the vesting, in whole or in part, of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2011 Plan, a corporate transaction is generally defined as the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

*Change of Control*. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. Under the 2011 Plan, a change of control is generally defined as (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction, (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity, (3) approval by the stockholders or our board of directors of a plan of complete dissolution or liquidation of us or our complete dissolution or liquidation occurs or (4) a consummated sale, lease or exclusive license or other disposition of all or substantially of our assets.

Certain options granted under the 2011 Plan, including the options held by our named executive officers, provide that if immediately prior to a change of control the participant's service with the Company has not terminated, the option will accelerate vesting with respect to 25% of the then-unvested portion of the option; if the option continues, the remaining 75% of the unvested option will continue to vest on the option's original schedule prior to the change of control and will accelerate vesting in full in the event that the participant's continuous service is terminated without cause or by the participant for good reason within the 12 months following the change of control. "Good reason" for purposes of this "double-trigger" provision is generally defined as (1) an assignment of duties or responsibilities to the participant that results in a material diminution of the participant's function; (2) a material reduction in the participant's annual base salary; (3) failure to continue the participant's benefit plans or programs, any action that would adversely affect the participant's participation in any benefit plan, reduce the participant's benefits under any benefit plan or deprive the participant of any fringe benefit; or (4) a relocation of the participant's business office more than 50 miles.

***2001 Stock Option Plan***

Our board of directors and our stockholders approved our 2001 Plan, which became effective in February 2001. The 2001 Plan terminated and no further awards were granted under the 2001 Plan upon the effective date of the 2011 Plan. As of December 31, 2016, there were outstanding stock options under our 2001 Plan covering a total of 74,681 shares of our common stock.

***2014 Employee Stock Purchase Plan***

*General.* Our board of directors adopted the ESPP in December 2014 and our stockholders approved the ESPP in April 2015. The ESPP became effective on May 5, 2015 in connection with our initial public offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP. Our board of directors has delegated its authority to administer the ESPP to our compensation committee.

The ESPP initially authorized the issuance of 110,820 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance automatically increases on January 1 of each calendar year, from January 1, 2016 through January 1, 2024 by the least of (1) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (2) 195,000 shares, or (3) a number determined by our board of directors that is less than (1) and (2).

*Offerings and Purchases.* The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. Generally, all regular employees, including executive officers, subject to certain restrictions, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (1) 85% of the fair market value of a share of our common stock on the first date of an offering or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

*Changes to Capital Structure.* In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year and (3) the number of shares and purchase price of all outstanding purchase rights.

*Corporate Transactions.* In the event of certain significant corporate transactions, including the consummation of: (1) a sale of all our assets, (2) the sale or disposition of 90% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately.

*Plan Amendments, Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

**401(k) Plan**

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. All participants' interests in their deferrals are 100% vested when contributed. In 2016, we made no matching contributions into the 401(k) plan. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions are deductible by us when made.

**Director Compensation**

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2016 to each of our non-employee directors:

| Name | Fees Earned ($) | Option Awards ($) (5) | Total ($) |
|---|---|---|---|
| Peter T. Bisgaard (4) | — | — | — |
| Harry A. George | 40,625 | 30,420 | 71,045 |
| Ann F. Hanham (1) | 14,700 | 26,100 | 40,800 |
| Donnie M. Hardison (2) | 24,887 | 43,660 | 68,547 |
| Mary F. Hoult (3) | 25,779 | — | 25,779 |
| James T. LaFrance | 40,407 | 27,960 | 68,367 |
| Lee R. McCracken | 46,562 | 27,960 | 74,522 |
| Lewis J. Shuster | 48,750 | 30,420 | 79,170 |

(1) Dr. Hanham's service on our board of directors began August 29, 2016.
(2) Mr. Hardison's service on our board of directors began May 2, 2016.

(3) Ms. Hoult's service on our board of directors ended August 25, 2016.
(4) Mr. Bisgaard waived compensation under our non-employee director compensation policy. Mr. Bisgaard resigned from our board of directors on March 2, 2017.
(5) As of December 31, 2016, the aggregate number of shares outstanding under all options to purchase our common stock held by our non-employee directors were: Mr. George: 12,000; Mr. LaFrance: 16,000; Mr. McCracken: 16,000; Mr. Shuster: 24,569; Mr. Hardison: 16,000 and Dr. Hanham: 10,000. None of the other directors listed in the table above held any options to purchase our common stock as of December 31, 2016. The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2015. These amounts have been computed in accordance with FASB ASC Topic 718, using the Black-Scholes option pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our financial statements included elsewhere in this Annual Report.

We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors, and will pay for the travel, lodging and other reasonable expenses incurred by our employee directors to attend meetings of our board of directors and, as applicable, committees of our board of directors.

We implemented a compensation policy for our non-employee directors upon completion of our IPO which provided that each such non-employee director received the following compensation for service on our board of directors:

- an annual cash retainer of $35,000;
- an additional annual cash retainer of $5,000 for service as chair of our board of directors;
- an additional annual cash retainer of $10,000, $5,000 and $2,500 for service as chair of our audit committee, compensation committee and nominating and governance committee, respectively;
- an automatic annual option grant to purchase 2,500 shares of our common stock for each non-employee director serving on the board of directors on the date of each annual stockholder meeting, in each case vesting monthly in equal installments over a one-year period such that the stock option is fully vested on the first anniversary of the date of grant; and
- upon first joining our board of directors an automatic initial option grant to purchase 5,000 shares of our common stock on the date of grant. One-third of the shares will vest twelve months after the date of grant and the remaining shares will vest monthly in equal installments over a two-year period thereafter such that the stock option is fully vested on the third anniversary of the date of grant. A director who, in the one year prior to his or her initial election to serve on the board of directors as a non-employee director, served as an employee of the company will not be eligible for an initial grant.

In April 2016, the non-employee director compensation policy was amended and restated such that non-employee director compensation for service on our board of directors is now as follows:

- an annual cash retainer of $35,000;
- an additional annual cash retainer of $30,000 for service as chair of our board of directors;
- an additional annual cash retainer of $15,000, $10,000 and $7,500 for service as the chair of our audit committee, compensation committee and nominating and governance committee, respectively;
- an additional annual cash retainer of $7,500, $5,000 and $3,750 for service as member of our audit committee, compensation committee and nominating and governance committee, respectively;
- an automatic annual option grant to purchase 6,000 shares of our common stock for each non-employee director serving on the board of directors on the date of each annual stockholder meeting, in each case vesting monthly in equal installments over a one-year period such that the stock option is fully vested on the first anniversary of the date of grant; and
- upon first joining our board of directors an automatic initial option grant to purchase 10,000 shares of our common stock on the date of grant. One-third of the shares will vest twelve months after the date of grant and the remaining shares will vest monthly in equal installments over a two-year period thereafter such that the stock option is fully vested on the third anniversary of the date of grant. A director who, in the one year prior to his or her initial election to serve on the board of directors as a non-employee director, served as an employee of the company will not be eligible for an initial grant.

Each of the option grants described above will vest and become exercisable subject to the director's continuous service with us through each applicable vesting date, provided that each option will vest in full upon a change of control, as defined under the 2014 Plan. The options will be granted under the 2014 Plan, the terms of which are described in more detail above under "– Equity Benefit Plans – 2014 Equity Incentive Plan."

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

**Securities Authorized for Issuance under Equity Compensation Plans**

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of December 31, 2016.

**Equity Compensation Plan Information**

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c ) |
|---|---|---|---|
| Equity compensation plans approved by security holders: | | | |
| 2001 Stock Option Plan | 74,681 | $ 5.77 | — |
| 2011 Equity Incentive Plan | 412,715 | 3.35 | — |
| 2014 Equity Incentive Plan (1) | 674,309 | 3.08 | 96,008 |
| 2014 Employee Stock Purchase Plan (2) | — | N/A | 99,300 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 1,161,705 | | 195,308 |

(1) On January 1 of each year from January 1, 2016 through and including January 1, 2024, the number of shares authorized for issuance under the 2014 Plan is automatically increased by a number equal to 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or such lesser number of shares determined by our board of directors. On January 1, 2016, the available shares for purchase under the 2014 Plan was increased by 273,769 shares.

(2) On January 1 of each year from January 1, 2016 through and including January 1, 2024, the number of shares authorized for issuance under our ESPP is automatically increased by a number equal to the least of: (a) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; (b) 195,000 shares; and (c) a number determined by the our board of directors that is less than the amounts set forth in the foregoing clauses (a) and (b). On January 1, 2016, the available shares for purchase under our ESPP was increased by 68,442 shares.

**Principal Stockholders**

The following table sets forth certain information regarding the ownership of the Company's common stock as of February 28, 2017 by: (i) each director; (ii) each of our executive officers named in the Summary Compensation Table above; (iii) all executive officers and directors of the Company as a group; and (iv) all those known by the Company to be beneficial owners of more than five percent of its common stock.

The table is based upon information supplied by officers, directors and principal stockholders, Schedules 13G filed with the SEC and other sources believed to be reliable by us. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 7,938,571 shares outstanding on February 28, 2017, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address for each person or entity listed in the table is c/o HTG Molecular Diagnostics, Inc., 3430 E. Global Loop, Tucson, Arizona 85706.

| | Common Stock Beneficially Owned | |
|---|---|---|
| Name and address of beneficial owner | Shares | Percentage |
| **Greater than 5% stockholders** | | |
| Novo A/S (1) | 1,280,185 | 16.0% |
| Turborg Havnevej 19 | | |
| DK-2900 Hellerup, Denmark | | |
| S.R. One Limited (2) | 1,092,781 | 13.7% |
| 161 Washington Street, Suite 500 | | |
| Conshohocken, PA 19428-2077 | | |
| QIAGEN NV (3) | 833,333 | 10.5% |
| Hulsterweg 82, 5912 PL | | |
| Venlo, The Netherlands | | |
| Merck Capital Ventures, LLC (4) | 785,140 | 9.9% |
| One Merck Drive | | |
| P.O. Box 1000 | | |
| Whitehouse Station, NJ 08889-0100 | | |
| FMR LLC (5) | 673,461 | 8.5% |
| 245 Summer Street | | |
| Boston, MA 02210 | | |
| Entities affiliated with Putnam Investments LLC (6) | 571,209 | 7.2% |
| One Post Office Square | | |
| Boston, MA 02109 | | |
| **Directors and named executive officers** | | |
| Timothy B. Johnson (7) | 282,423 | 3.5% |
| John L. Lubniewski (8) | 118,004 | 1.5% |
| Patrick C. Roche, Ph.D. (9) | 84,724 | 1.1% |
| Harry A. George (10) | 154,366 | 1.9% |
| Ann F. Hanham, Ph.D. | — | * |
| Lewis J. Shuster (11) | 22,569 | * |
| Lee McCracken (12) | 9,131 | * |
| James T. LaFrance (13) | 8,572 | * |
| Donnie M. Hardison (14) | 4,000 | * |
| **All current executive officers and directors as a group (11 persons) (15)** | 835,030 | **9.9%** |

* Represents beneficial ownership of less than one percent.

(1) Includes 49,786 shares issuable upon the exercise of warrants. The board of directors of Novo A/S, a Danish limited liability company, consists of Sten Scheibye, Göran Ando, Jeppe Christiansen, Steen Riisgaard and Per Wold-Olsen, who have shared investment and voting control with respect to the shares held by Novo A/S and may exercise such control only with the support of a majority of the members of the Novo A/S board of directors. No individual member of the Novo A/S board of directors is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo A/S.

(2) Includes 43,538 shares issuable upon the exercise of warrants. Voting and/or dispositive powers with respect to shares held in the name of S.R. One Limited are exercised by S.R. One Limited through a collective vote of S.R. One Limited's principals, on a majority vote basis.

(3) The 833,333 shares of common stock are held of record by QIAGEN North American Holdings, Inc., a wholly-owned subsidiary of QIAGEN N.V.

(4) Includes 28,436 shares issuable upon the exercise of warrants.

(5) Abigail P. Johnson is a director, the Vice Chairman, the Chief Executive Officer and President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of the FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other

Series B shareholders have entered into a shareholders'' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of the Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FRM LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act advised by Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by Fidelity Funds' Board of Trustees. This information is based on the Schedule 13G filed on February 12, 2016 with the SEC.

(6) The number of shares beneficially owned consists of (a) 543,544 shares held by Putnam Investment Management and (b) 27,665 shares held by The Putnam Advisory Company, LLC, both wholly owned subsidiaries of Putnam Investments, LLC. Putnam Investment Management is the investment adviser to the Putnam family of mutual funds and the Putnam Advisory Company, LLC is the investment adviser to Putnam's institutional clients. Both subsidiaries have dispositive power over the shares as investment managers. In the case of shares held by the Putnam mutual funds managed by Putnam Investment Management, LLC, the mutual funds, through their boards of trustees, have voting power. Unless otherwise indicated, The Putnam Advisory Company, LLC has sole voting power over the shares held by its institutional clients. This information is based on the Schedule 13G/A filed on February 14, 2017 with the SEC.

(7) Includes 210,210 shares that Mr. Johnson has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(8) Includes 81,215 shares that Mr. Lubniewski has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(9) Includes 53,810 shares that Dr. Roche has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(10) Consists of shares beneficially owned by Solstice Capital II LP. Mr. George is the managing member of Solstice Capital and has joint voting and investment power over the shares held by Solstice Capital II LP.

(11) Includes 22,569 shares that Mr. Shuster has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(12) Includes 9,131 shares that Mr. McCracken has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(13) Includes 8,572 shares that Mr. LaFrance has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(14) Includes 4,000 shares that Mr. Hardison has the right to acquire from us within 60 days of February 28, 2017 pursuant to the exercise of stock options.

(15) The number of shares beneficially owned consists of (a) the shares described in Notes (7) through (14), and (b) 61,022 shares beneficially owned, 90,219 shares issuable upon exercise of options within 60 days of February 28, 2017 pursuant to the exercise of stock options.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds the lesser of $120,000 or one percent of the average of the Company's total assets at year-end for the last two completed fiscal years.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A "related person" is any executive officer, director or a holder of more than five percent of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

The following sections summarize transactions since January 1, 2014 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of $120,000 or one percent of the average of the Company's total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive Compensation" and "Director Compensation."

*Preferred Stock and Warrant Financings*

From February 4, 2014 through March 31, 2014, we issued and sold to investors in two closings an aggregate of 34,453,538 shares of our Series E preferred stock at a purchase price of $0.2189 per share, for aggregate consideration of $7.5 million. We also issued to investors in our Series E preferred stock financing warrants to purchase up to an aggregate of 11,484,503 shares of our Series E preferred stock at an issue price of $0.0001 per share underlying the warrants, for aggregate consideration of $1,148. The Series E warrants were exercisable for $0.001 per share and were each exercised immediately upon issuance for an aggregate cash purchase price of $11,484.

The participants in these preferred stock financings included the following executive officers, directors and holders of more than 5% of our capital stock:

| Participants | Series E Preferred Stock (1) |
|---|---|
| **Executive Officers and Directors** | |
| Timothy B. Johnson | 60,910 |
| John L. Lubniewski | 76,138 |
| Shaun D. McMeans | 152,276 |
| Debra A. Gordon | 7,646 |
| James R. Weersing (2) | 609,106 |
| **5% or Greater Stockholders** | |
| Novo A/S | 15,227,653 |
| S.R. One, Limited | 15,227,653 |
| Merck Capital Ventures, LLC | 7,613,826 |
| Entities affiliated with Fletcher Spaght Associates | 6,091,062 |

(1) Includes the shares of Series E preferred stock issued to the participant upon exercise of the Series E preferred stock warrants issued in the financing.
(2) Mr. Weersing served on our board of directors until April 2015. Mr. Weersing participated in the financings through his affiliated family trust.

Certain of our former directors were affiliated with the investors that participated in the preferred stock financings described above, as indicated in the table below:

| Director | Principal Stockholder |
|---|---|
| Peter T. Bisgaard (1) | Novo A/S |
| Simeon J. George, M.D. (2) | S.R. One Limited |
| Mary F. Hoult (3) | Fletcher Spaght Associates |
| Larry Senour (4) | Merck Capital Ventures, LLC |

(1)Mr. Bisgaard resigned from our board of directors in March 2017.
(2)Dr. George resigned from our board of directors in October 2015.
(3)Ms. Hoult's service on our board of directors ended in August 2016.
(4)Mr. Senour resigned from our board of directors in May 2015.

*Convertible Note and Warrant Financings*

In December 2014, we entered into two separate note and warrant purchase agreements, or collectively, the 2014 note purchase agreements, with certain of our existing investors, including beneficial owners of more than 5% of our capital stock and certain entities affiliated with members of our board of directors. The first note and warrant purchase agreement, or the first note purchase agreement, provided for the sale and issuance by us of up to an aggregate of $7.3 million in principal amount of convertible notes in a series of closings, each of which were to be approved by the unanimous vote or written consent of those members of our board of directors who were not an affiliate of any of the investors under such agreement. The second note and warrant purchase agreement, or the second note purchase agreement, provided for the sale and issuance by us of up to an aggregate of $6.2 million in principal amount of convertible notes in a series of closings, each of which were to be approved by (i) our board of directors, including a majority of the directors elected by the holders of our Series E preferred stock, and (ii) investors whose purchase amount for such closing equaled or exceeded 50% of the aggregate principal amount of notes to be sold at such closing. Notes issued under the 2014 note purchase agreements accrued interest at a rate of 8% per annum, compounded annually, and became due and payable on March 31, 2016, subject to their earlier conversion in the event we completed an initial public offering in which we received gross offering proceeds of at least $20.0 million from the sale of shares to investors who were not holders of our securities, or a qualified initial public offering, or a private placement of our preferred stock (whether in one single transaction or several tranches) resulting in aggregate gross proceeds of at least $20.0 million from sales of securities to investors who were not holders of our securities, or a qualified private placement of our equity securities. The number of shares into which the notes may be converted, common shares in the case of a qualified initial public offering or preferred shares in the case of a qualified private placement, was equal to the outstanding principal and accrued interest divided by the price per share paid by investors purchasing such newly issued equity securities. Certain provisions of the first note purchase agreement terminated (including the investors' obligations to purchase notes thereunder) immediately prior to the earlier to occur of the closing of (i) a qualified initial public offering or (ii) a qualified private placement and certain provisions of the second note purchase agreement terminated (including the investors' obligations to purchase notes thereunder) immediately prior to the earlier to occur of (x) the time at which a registration statement covering a public offering of our securities under the Securities Act of 1933, as amended, becomes effective or (y) the initial closing of a qualified private placement. Such provisions of the 2014 note purchase agreements (including the investors' obligations to purchase notes thereunder) terminated in connection with the closing of our IPO in May 2015. In February, March and April 2015, we issued an aggregate of $4.5 million in principal amount of the 2015 notes to investors in three closings under the first note purchase agreement. There were no draws under the second note purchase agreement prior to our IPO in May 2015.

In January 2015, in connection with the 2014 note purchase agreements, we issued warrants, or the 2015 warrants, which were initially exercisable for an aggregate of 9,311,586 shares of our Series E preferred stock at an exercise price of $0.2189 per share. In connection with the closing of our IPO, the 2015 warrants became exercisable for an aggregate of 144,772 shares of our common stock at an exercise price of $14.00 per share.

The participants in these convertible note and warrant financings included the following holders of more than 5% of our capital stock:

| Participants | Shares of Series E Preferred Stock Underlying 2015 Warrants | Aggregate Principal Amount of 2015 Notes (in thousands) (1) |
|---|---|---|
| **Directors** | | |
| James R. Weersing | 51,126 | — |
| **5% or Greater Stockholders** | | |
| Novo A/S | 3,184,170 | 1,535 |
| S.R. One, Limited | 2,784,593 | 1,535 |
| Merck Capital Ventures, LLC | 1,818,681 | 768 |
| Entities affiliated with Fletcher Spaght Associates | 1,358,988 | 614 |

(1) Includes amounts purchased in note closings in February, March and April 2015.

*Investor Rights Agreement*

In connection with our preferred stock financings, we entered into an Amended and Restated Investor Rights Agreement containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our convertible preferred stock and certain holders of our common stock. In connection our IPO, we entered into a further Amended and Restated Investor Rights Agreement with these holders which eliminated all of the rights and obligations provided in the first Amended and Restated Investor Rights Agreement, except for the registration rights granted under the new agreement. The holders of at least 50% of the registrable securities have the right to make up to two demands that we file a registration statement under the Securities Act covering such holders' registrable securities then outstanding (provided that the anticipated aggregate offering price of securities requested to be sold under such registration statement is at least $7.5 million), subject to specified exceptions, conditions and limitations. If we are eligible to file a registration statement on Form S-3, the holders of at least 50% or more of the outstanding registrable securities have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of securities to be sold under the registration statement on Form S-3 is at least $5.0 million, subject to specified exceptions, conditions and limitations. If we propose to register any securities for public sale, holders of registration rights will have the right to include their shares in the registration statement (except with respect to this offering, for which the holders have waived any and all rights to have their shares included). The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement, subject to specified conditions and limitations. Generally, we are required to bear all registration and selling expenses incurred in connection with the demand, piggyback and Form S-3 registrations described above, other than underwriting discounts and commissions. The demand, piggyback and Form S-3 registration rights discussed above will terminate in May 2017 or, as to a given holder of registrable securities, when such holder is able to sell all of its registrable securities in a single 90-day period under Rule 144 of the Securities Act.

*Employment Arrangements*

We currently have written employment agreements with our executive officers. For information about our employment agreements with our named executive officers, refer to "Executive Compensation – Agreements with our Named Executive Officers."

*Stock Options Granted to Executive Officers and Directors*

We have granted stock options to our executive officers and directors, as more fully described in "Executive Compensation – Outstanding Equity Awards at Fiscal Year-End."

*Indemnification Agreements*

We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

**Director Independence**

Our board of directors has determined that all of our directors other than Mr. Johnson are independent directors, as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules. The NASDAQ independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by NASDAQ rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management.

**Item 14. Principal Accounting Fees and Services.**

The following table summarizes the fees of BDO USA, LLP, our independent registered public accounting firm, for 2016 and 2015.

| | December 31, | |
|---|---|---|
| | 2016 | 2015 |
| **Fee Category** | | |
| Audit fees (1) | $ 297,997 | $ 420,471 |
| Audit-related fees | — | — |
| Tax fees | — | — |
| All other fees | — | — |
| Total fees | $ 297,997 | $ 420,471 |

(1) Audit fees consist of fees for professional services provided primarily in connection with the audit of our annual financial statements, review of our quarterly financial statements and our initial public offering in 2015.

**Pre-Approval Policies and Procedures**

Pursuant to its charter, the audit committee must review and approve, in advance, the scope and plans for the audits and the audit fees and approve in advance (or, where permitted under the rules and regulations of the SEC, subsequently) all non-audit services to be performed by the independent auditor that are not otherwise prohibited by law and any associated fees. The audit committee may delegate to one or more members of the committee the authority to pre-approve audit and permissible non-audit services, as long as this pre-approval is presented to the full committee at scheduled meetings. All fees described above were pre-approved by the audit committee.

## PART IV

**Item 15. Exhibits, Financial Statement Schedules.**

(a)(1) Financial Statements - The financial statements filed as part of this Annual Report on Form 10-K are listed on the Index to Financial Statements in Item 8.

(a)(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits.

The exhibits listed on the Exhibit Index (following the Signatures section of this report) are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

**Item 16. Form 10-K Summary.**

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

HTG Molecular Diagnostics, Inc.

Date: March 23, 2017

By: /s/ Timothy B. Johnson
**Timothy B. Johnson**
*President and Chief Executive Officer*
*(Principal Executive Officer)*

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Timothy Johnson and Shaun D. McMeans, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated:

| Signature | Title | Date |
|---|---|---|
| /s/ Timothy B. Johnson<br>Timothy B. Johnson | President, Chief Executive Officer and Member of the Board of Directors<br>*(Principal Executive Officer)* | March 23, 2017 |
| /s/ Shaun D. McMeans<br>Shaun D. McMeans | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | March 23, 2017 |
| /s/ Ann F. Hanham<br>Ann F. Hanham | Chair of the Board of Directors | March 23, 2017 |
| /s/ Harry A. George<br>Harry A. George | Member of the Board of Directors | March 23, 2017 |
| /s/ James T. LaFrance<br>James T. LaFrance | Member of the Board of Directors | March 23, 2017 |
| /s/ Lee R. McCracken<br>Lee R. McCracken | Member of the Board of Directors | March 23, 2017 |
| /s/ Lewis J. Shuster<br>Lewis J. Shuster | Member of the Board of Directors | March 23, 2017 |
| /s/ Donnie M. Hardison<br>Donnie M. Hardison | Member of the Board of Directors | March 23, 2017 |

## 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 C-2 Preferred Stock Warrant issued by the Registrant to Silicon Valley Bank, dated December 24, 2008 (incorporated by reference to Exhibit 4.3 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 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). |
| 4.6 | 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). |
| 4.7 | 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). |
| 4.8 | 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). |
| 4.9 | 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). |
| 10.1+ | Form of Indemnity Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 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). |
| 10.2+ | HTG Molecular Diagnostics, Inc. 2001 Stock Option Plan and Forms of Stock Option Agreement and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 10.2 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). |
| 10.3+ | HTG Molecular Diagnostics, Inc. 2011 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 10.3 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). |
| 10.4+ | HTG Molecular Diagnostics, Inc. 2014 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-203930), filed with the SEC on May 7, 2015). |

| Exhibit Number | Description |
|---|---|
| 10.5+ | HTG Molecular Diagnostics, Inc. 2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 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). |
| 10.6+ | HTG Molecular Diagnostics, Inc. Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quafterly Report on Form 10-Q, filed with the SEC on August 9, 2016). |
| 10.7+ | Employment Letter Agreement dated December 24, 2014 by and between the Registrant and Timothy Johnson (incorporated by reference to Exhibit 10.7 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). |
| 10.8+ | Employment Letter Agreement dated December 18, 2014 by and between the Registrant and John Lubniewski (incorporated by reference to Exhibit 10.8 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). |
| 10.9+ | Employment Letter Agreement dated December 15, 2014 by and between the Registrant and Debra Gordon (incorporated by reference to Exhibit 10.9 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). |
| 10.10+ | Employment Letter Agreement dated December 15, 2014 by and between the Registrant and Shaun McMeans (incorporated by reference to Exhibit 10.10 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). |
| 10.11+ | Employment Letter Agreement dated December 15, 2014 by and between the Registrant and Patrick Roche (incorporated by reference to Exhibit 10.11 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). |
| 10.12 | Standard Commercial-Industrial Multi Tenant Triple Net Lease dated July 11, 2008 by and between the Registrant and Pegasus Properties LP (incorporated by reference to Exhibit 10.12 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). |
| 10.13 | Standard Commercial-Industrial Multi Tenant Triple Net Lease dated May 11, 2011 by and between the Registrant and Pegasus Properties LP (incorporated by reference to Exhibit 10.13 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). |
| 10.14* | First Amendment to Lease Agreement (Suite 100 – Administration), dated August 4, 2015, by and between Pegasus Properties, L.P. and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2015). |
| 10.15* | First Amendment to Lease Agreement (Suite 300 – Laboratory), dated August 4, 2015, by and between Pegasus Properties, L.P. and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2015). |
| 10.16 | Loan and Security Agreement, dated August 22, 2014, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.15 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). |
| 10.17 | First Amendment to Loan and Security Agreement and First Amendment to Disbursement Letter, dated August 4, 2015, by and between Registrant, Oxford Finance LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 7, 2015). |
| 10.18 | Termination of Security Agreement, Release of Security Interest and Understanding Regarding Asset Purchase Agreement, dated August 22, 2014, by and between the Registrant and NuvoGen Research LLC (incorporated by reference to Exhibit 10.16 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). |
| 10.19* | IVD Test Development and Component Supply Agreement, dated October 15, 2014, by and between the Registrant and Illumina, Inc. (incorporated by reference to Exhibit 10.17 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). |

| Exhibit Number | Description |
|---|---|
| 10.20 | HTG Molecular Diagnostics, Inc. Amended and Restated Stock Purchase Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2016). |
| 10.21* | Authorization, Supply, and Regulatory Authorization Agreement, dated March 16, 2016, by and between HTG Molecular Diagnostics, Inc. and Life Technologies Corporation (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 21, 2016). |
| 10.22 | Second Amendment to Loan and Security Agreement, dated June 1, 2016, by and between Registrant, Oxford Finance LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2016). |
| 10.23* | Master Assay Development, Commercialization and Manufacturing Agreement, dated November 16, 2016, by and between Registrant and QIAGEN Manchester Limited. |
| 10.24 | Stock Purchase Agreement, dated November 16, 2016, by and between Registrant and QIAGEN North American Holdings, Inc. |
| 23.1 | Consent of Independent Registered Public Accounting Firm. |
| 24.1 | Power of Attorney. Reference is made to the signature page hereto. |
| 31.1 | Certification of Principal Executive Officer 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. |
| 31.2 | Certification of Principal Financial Officer 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. |
| 32.1 | Certification of 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 Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

* We have requested confidential treatment for certain portions of this agreement. Omitted portions have been filed separately with the SEC.
\+ Indicates management contract or compensatory plan.

# MASTER ASSAY DEVELOPMENT, COMMERCIALIZATION AND MANUFACTURING AGREEMENT

This Master Assay Development, Commercialization and Manufacturing Agreement ("Agreement"), is entered into and effective as of November 16, 2016 (the "Effective Date"), by and between QIAGEN Manchester Limited, a UK corporation having offices at Skelton House, Lloyd Street North, Manchester, UK ("QIAGEN"), and HTG Molecular Diagnostics, Inc., a Delaware corporation having offices at 3430 E. Global Loop, Tucson, AZ, U.S.A. 85706 ("HTG"). HTG and QIAGEN are herein referred to each as a "Party" and collectively as the "Parties."

## RECITALS

A. QIAGEN is a leading provider of sample to insight technologies, including, *inter alia*, sequencing equipment and bioinformatics analytics, and companion diagnostic assays to aid in the selection and use of pharmaceutical products for the treatment of disease;

B. HTG is a leading provider of novel technologies based on targeted nuclease protection chemistry to facilitate the routine use of complex molecular profiling in a multiplexed panel format from low amounts of samples, which is useful *inter alia* for companion diagnostic assays;

C. QIAGEN and HTG desire to engage in a collaborative relationship, involving performing collaborative assay development and manufacturing activities involving each Party's applicable technology, which is intended to support QIAGEN's entering into companion diagnostic development programs with third party pharmaceutical companies, and, if applicable and agreed to by the Parties in each case, to facilitate QIAGEN's or HTG's existing, independent programs;

D. Each Party desires to engage in such collaborative development and commercial activities in accordance with the terms and conditions of this Agreement and individual Statements of Work (as defined below) entered into by the Parties.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual obligations and responsibilities of the Parties as set forth herein, the receipt and total sufficiency of which is hereby acknowledged, the Parties agree as follows:

## AGREEMENT

### 1. DEFINITIONS

**1.1** "**Affiliate**" means, with respect to a Party, any corporation, partnership or other business organization that, directly or indirectly, controls, is controlled by or is under common control with such Party. For the purpose of this definition "control" (with correlative meanings for the terms "controlled by" and "under common control with") shall mean that the applicable business organization has the actual ability to direct and control the management and business decisions of the applicable Party, including by holding more than 50% (fifty percent) of the voting stock or other ownership interests of the applicable corporation or business entity.

**1.2** **"AM Field"** means the development and commercialization of companion diagnostic assays in the PDP Field for use in connection with autoimmune or microbiome therapeutics developed by Sponsors.

**1.3** "**Applicable Law(s)**" means all applicable provisions of all statutes, laws, rules, regulations, administrative codes, ordinances, decrees, orders, decisions, injunctions, awards, judgments, permits and licenses of or from Federal, State and local governmental authorities, including regulatory authorities, as the same may be amended from time to time, that are applicable to the particular obligation, task or undertaking under this Agreement.

**1.4** "**Change of Control**" means, with respect to a Party, either (a) a sale of all or substantially all of such Party's assets or business to which this Agreement relates; (b) a merger or consolidation of such Party in which the stockholders of such Party immediately prior thereto do not own, directly or indirectly, either (x) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger or consolidation or (y) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger or consolidation, in each case in substantially the same proportion as their ownership of the outstanding voting securities of such Party immediately prior to such transaction; or (c) a transaction or series of transactions that result in any Exchange Act Person becoming the owner, directly or indirectly, of securities of such Party representing more than fifty percent (50%) of the combined voting power of such Party's then-outstanding securities (other than by virtue of a merger or consolidation and excluding any acquisition of securities of such Party directly from such Party).

**1.5** **Confidential Information**" means, with respect to a Party, all proprietary and/or confidential information of such Party (the "Disclosing Party" as to such information) provided orally or in writing to the other Party (the "Receiving Party" as to such information), or as observed by such Receiving Party on visits to the Disclosing Party's facilities, which may include any information that relates to the Disclosing Party's new or existing products, services and/or business operations, product development plans, standard operating procedures, specifications, pricing information, business methods, trade secrets, business processes, business plans, inventions, techniques, and other information not readily available to the public, whether or not labeled as "Confidential" or "Proprietary" or otherwise reduced to writing, but *provided that* "Confidential Information" shall not include any information that meets any of the exclusions in Section 6.5. For purposes of this Agreement, the Party disclosing its Confidential Information hereunder shall be referred to as "Disclosing Party" with respect to such information, while the Party receiving the Disclosing Party's Confidential Information hereunder shall be referred to as the "Receiving Party" as to such information. In addition, all HTG IP shall be deemed the Confidential Information of HTG, and all QIAGEN IP shall be deemed the Confidential Information of QIAGEN, subject in each case to information that meets any of the exclusions in Section 6.5.

**1.6** **"Cost of Goods"** means, with respect to a particular HTG or QIAGEN instrument or tool or other product (excluding any PDP Assay) sold or transferred as contemplated in Section 5.2.3, all costs and expenses actually incurred by HTG or QIAGEN (as applicable) with respect to such instrument or tool or other product that are appropriately characterized as "cost of goods sold" in accordance with U.S. GAAP (including any costs and expenses allocated to "cost of goods sold" in a manner consistent with HTG or QIAGEN's (as applicable) past practices in preparation of its audited financial statements).

**1.7** **"Intellectual Property Rights**" means all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (i) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, and mask works; (ii) trademark and trade name rights and similar rights; (iii) trade secret rights; (iv) patent rights and industrial property rights; and (v) other proprietary rights in intellectual property of every kind and nature.

**1.8** "**Exchange Act Person**" means any natural person, entity or "group" (within the meaning of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder), except that "Exchange Act Person" will not include an underwriter temporarily holding securities pursuant to a registered public offering of such securities.

**1.9** **"Fields"** means:

**1.9.1** the Oncology Field, which shall be exclusive as between the Parties (including their Affiliates) as provided in Section 2.3.1;

**1.9.2** the AM Field, which shall be non-exclusive as between the Parties as provided in Section 2.3.2; and

**1.9.3** any other companion diagnostics field mutually agreed by the Parties to be included in this Agreement with respect to the Parties' development and commercialization of companion diagnostic assays in the PDP Field for use applicable to such field(s) as provided in Section 2.3.2.

**1.10** "**HTG IP**" means all Inventions that: (a) were made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of HTG, its employees, agents or contractors, individually or jointly, or jointly with third parties, prior to the Effective Date, or (b) were made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of HTG, its employees, agents or contractors, individually or jointly during the Term (defined below) and independent of Development work performed under this Agreement, (c) are made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of HTG, its employees, agents or contractors, individually or jointly, during the Term in connection with the performance of Development work under this Agreement, and are not directly related to and specifically derived from any QIAGEN Property; or (d) were made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of QIAGEN or any of its Affiliates, or their respective employees, agents or contractors, individually or jointly, during the Term either (i) with reference to or use of HTG Property received by QIAGEN in connection with this Agreement, or (ii) in connection with the performance of Development work under this Agreement, in each case that directly relate to NPA Chemistry, which is defined as any practice, process, procedure, method, methodology, technique, technology, material or the like for targeted nuclease protection and subsequent detection, by whatsoever means, of nucleic acid molecules, including DNA or RNA in whatsoever form existing in nature or otherwise, that need not (but, optionally, may) be substantially purified prior to nuclease protection. For the purposes of clarity, HTG IP shall not include any QIAGEN IP.

**1.11** "**HTG Property**" means: (i) HTG IP and (ii) HTG's Confidential Information.

**1.12** **"Inventions"** means all inventions, discoveries, know-how, trade secrets, devices, apparatus, practices, processes, procedures, methods, methodologies, techniques, products, trade secrets, notes, data, written materials, findings, records and documents, works of authorship, software and any other Intellectual Property Rights, including improvements, enhancements, or derivatives to or of any of the foregoing, whether or not patentable or otherwise protectable by intellectual property rights.

**1.13** **"Sponsor Project Agreement** means an agreement entered into between QIAGEN and a Sponsor to conduct one or more Projects.

**1.14** **"Net Profits"** means, as to a particular SOW, the following: (a) all total amounts paid by the applicable Sponsor to QIAGEN under the relevant Sponsor Project Agreement with respect to the conduct of the Project covered by such SOW, less (b) the sum of QIAGEN Project Costs plus HTG Project Costs.

**1.15** **"Project"** means a project covered by a particular Sponsor Project Agreement, under which QIAGEN, in partnership with HTG under this Agreement and an SOW, would develop a PDP Assay applicable to the Sponsor therapeutic covered by such Project, obtain needed regulatory approval of such PDP Assay, and would commercialize such PDP Assay throughout the Territory, after regulatory approval, as a companion diagnostic assay for use in connection with the prescribing of applicable Sponsor therapeutic(s) that are the subject of such Project.

**1.16** "**Project Costs**" means, with respect to a Party, the actual, direct costs incurred by the applicable Party to conduct its Development work under, and as mutually agreed in, a particular SOW. [***…]

**1.17** **"PDP Field"** means use of diagnostic assays utilizing next generation sequencing ("NGS") detection solely in connection with clinical applications of therapeutics, whether in connection with clinical trials of a therapeutic or in patient clinical settings (to determine if the clinical trial participant or the patient is an appropriate candidate for the applicable therapy), and whether as a companion diagnostic to a particular therapy or as a complementary diagnostic for the treatment pathway. All other uses of NGS-based assays, […***…] are expressly excluded from the PDP Field unless a particular Project […***…] expressly contemplate a preliminary feasibility study, which would otherwise constitute an Excluded Use, as an intermediate step in the clinical development program for the applicable therapeutic. […***…]. For clarification, PDP Field expressly excludes PCR and other non-NGS assay technology platforms or any other project or business between QIAGEN and its customers for QIAGEN's bioinformatics "software as a service" business.

**1.18** "**"Oncology Field"** means the development and commercialization of companion diagnostic assays in the PDP Field for use in connection with cancer therapeutics developed by Sponsors.

**1.19** **"QIAGEN IP**" means all Inventions that (a) were made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of QIAGEN, its employees, agents or contractors, individually or jointly, or jointly with third parties, prior to the Effective Date, or (b) were made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of QIAGEN, its employees, agents or contractors, individually or jointly, during the Term and independent of Development work performed under this Agreement; or (c) are made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of QIAGEN, it employees, agents or contractors, individually or jointly, in connection with the performance of Development work conducted under this Agreement, and are not directly related to and specifically derived from any HTG Property, or (d) were made, developed, perfected, devised, conceived of or first reduced to practice by or on behalf of HTG or its Affiliate, or their respective employees, agents or contractors, individually or jointly, during the Term in connection with the performance of Development work under this Agreement that directly relate to or is specifically derived from any QIAGEN Property. For the purposes of clarity, QIAGEN IP shall not include any HTG IP

**1.20** "**PDP Assay**" means an NGS-based companion diagnostic assay developed by the Parties pursuant to a particular SOW. It is understood that, as provided in an applicable Statement of Work (and subject to any exceptions set forth therein, QIAGEN shall market and sell such assay under QIAGEN's brand name and, if mutually agreed in the applicable Statement of Work, referencing a brand or technology of HTG if such HTG IP has been used.

**1.21** **"Protocol"** means, with respect to a particular Project, the protocol agreed to by QIAGEN and the applicable Sponsor to cover the Sponsor's activities to support such Project, including delivery of relevant clinical samples, and conduct of clinical trials on its applicable therapeutic, involving use of the applicable PDP Assay being developed hereunder pursuant to such Project.

**1.22** **"QIAGEN Property**" means: (i) the QIAGEN IP; (ii) the QIAGEN Materials; and (iii) QIAGEN's Confidential Information.

**1.23** "**QIAGEN Materials**" means: (i) all test materials, controls, specimens or samples ("**Samples**") identified in the applicable Statement of Work, collected from subjects in accordance with the Protocol (defined above) applicable to a particular Project under an Sponsor Project Agreement; and (ii) all reagents, data and information relating to the Samples or the use of the Samples provided by QIAGEN and/or the applicable Sponsor to HTG for purposes of performing its Development work pursuant to such Statement of Work.

**1.24** **"Statement of Work"** or **"SOW"** means a statement of work, as provided in Section 3, which is executed by the Parties to cover the performance by each Party of its respective Development activities in support of development of the PDP Assay in connection with the related Project. Each such SOW shall be subject to and governed by the terms of this Agreement.

**1.25** **"Development"** means the assay development activities undertaken by HTG and/or QIAGEN to develop a particular PDP Assay for a particular Project, as specified in detail in the applicable Statement of Work.

**1.26** "**Sponsor**" shall mean any pharmaceutical company or companies that is party to a particular Sponsor Project Agreement, and is identified in the relevant Statement of Work, for whom QIAGEN (in partnership with HTG under this Agreement) is engaged in a Project.

**1.27** **"Steering Committee"** means the committee formed by the Parties under Section 2.4, to manage and oversee the negotiation of Sponsor Project Agreements, the conduct of Development work under the

agreed SOWs, the manufacture of PDP Assays, and the commercialization by QIAGEN of approved PDP Assays (and related QIAGEN equipment and tools).

**1.28** "**Territory**" means worldwide.

**1.29** Other capitalized terms used in this Agreement shall have the meanings elsewhere defined in this Agreement.

## 2. COMPANION DIAGNOSTICS PARTNERSHIP

**2.1** Overview of Collaboration. This Agreement shall serve as the master agreement for the collaboration of the Parties to develop, pursuant to Projects initiated under Sponsor Project Agreements, and commercialize PDP Assays in the Fields for use solely in the PDP Field. Under such collaboration, the Parties shall jointly seek and negotiate with potential Sponsors, to enter into Sponsor Project Agreements under which specific agreed Projects will be conducted to develop PDP Assays in the Fields, which shall be run on QIAGEN sequencing equipment (often in connection with QIAGEN bioinformatics analysis programs, and other QIAGEN proprietary tools, and/or with proprietary HTG tools and instruments as well), and which are to be used as companion diagnostics in the PDP Field to support the applicable Sponsor's therapeutic development and commercialization. The development of each PDP Assay, in connection with a Project under a particular Sponsor Project Agreement, shall be conducted by the Parties collaboratively under the applicable Statement of Work, as agreed to by the Parties as discussed in Section 3.2, in connection with QIAGEN agreeing to conduct such Project. It is expected that: (a) for each Project that relates to PDP Assays based primarily on HTG IP (such as, RNA-targeted assays, HTG shall conduct most of the preliminary Development work to create the a particular PDP Assay, (b) for each Project that relates to PDP Assays based primarily on QIAGEN IP (such as, certain DNA-targeted assays), QIAGEN likely will conduct most of the preliminary Development work to create the a particular PDP Assay, and (c) once such work Development work is completed, the clinical and regulatory work needed to obtain needed regulatory approvals of the PDP Assay shall be conducted by QIAGEN in collaboration with the applicable Sponsor. It is also expected that HTG shall manufacture and supply to QIAGEN, for its use in clinical development and commercialization, the HTG-developed PDP Assays, pursuant to the manufacturing provisions of a Supply Agreement to be entered into by the Parties as contemplated in Section 8.3, and that QIAGEN shall have the responsibility for marketing, selling and otherwise commercializing the PDP Assays.

**2.2** Sponsor Project Agreements; Projects. The Parties shall seek to identify, and shall negotiate with, appropriate pharmaceutical companies regarding entering into Sponsor Project Agreements with QIAGEN, covering one or more Projects to develop PDP Assays for use in the PDP Field as companion diagnostic assays in connection with such company's applicable therapeutics. Each of the Parties commits to be fully cooperative with the other and to use good faith, diligent and commercially reasonable efforts, in all such activities seeking Sponsor Project Agreements. [***…] The Parties' discussion and management of the Sponsor Project Agreement negotiation process shall be primarily through the Steering Committee.

**2.3** Exclusivity, Non-exclusivity and Related Matters.

**2.3.1** The Parties agree that their relationship under this Agreement regarding the Oncology Field shall be exclusive, as provided herein, but subject to the exceptions below. Each Party agrees that if it (or any of its Affiliates) becomes aware of any pharmaceutical company that likely is interested in, or that the Party believes would be a good candidate for, entering into an agreement or other relationship to develop a PDP Assay in the Oncology Field (whether in development or in commercialization), such Party shall, subject to the appropriate consent of the pharmaceutical company, notify the other Party of such company and all relevant information regarding its cancer therapeutic and possible interest in a companion diagnostic deal. The Parties then shall promptly meet (most appropriately through the Steering Committee) and discuss such opportunity and determine whether (and if so, how) to approach such company to discuss a possible Sponsor Project Agreement, as contemplated under Section 2.2. If, as to any such pharmaceutical company, either (a) the Parties are not able to agree on the Key Terms of the Sponsor Project Agreement with such company, or such company determines not to enter into a proposed Sponsor Project Agreement, or (b) the company indicates [***…] or (c) as to a particular proposed Project, the Parties cannot agree on the terms of an appropriate SOW to cover the Development work needed for such proposed Project, then, in case of scenario (a) or (b), the Parties (including their Affiliates) shall not independently work with such pharmaceutical company in the Oncology field, and, in case of scenario (c), the Parties (including their Affiliates) shall not independently work with such pharmaceutical company with respect to the Project (or any project that is substantially similar) in the Oncology Field; provided that, for clarification, with respect to scenario (c), QIAGEN and its Affiliates shall be unrestricted to work, in conformance with the terms and conditions of this Agreement, with such pharmaceutical company on a QIAGEN-developed, DNA-based PDP Assay. In addition, for clarity, the above exclusivity commitments in the Oncology Field remain as to all other companies and possible projects in the Oncology Field.

**2.3.2** With respect to possible Projects in Fields other than the Oncology Field, the Parties acknowledge and agree that their relationship under this Agreement is non-exclusive. Any collaborative program of the Parties hereunder to develop a PDP Assay for any Field other than the Oncology Field shall be undertaken only if the Parties agree, in their sole and absolute discretion, on the applicable Sponsor Project Agreement and SOW for such program, with neither Party having an obligation so to agree. If either Party desires to engage in such a non-oncology program hereunder, it may request the other Party to consider the proposed program, and the Parties then will discuss reasonably and in good faith the proposed program, including the applicable pharmaceutical company of interest in the program, and the proposed Sponsor Project Agreement and SOW. If the Parties can agree on such items, the program will proceed hereunder as a Project under the applicable agreed Sponsor Project Agreement and SOW. Neither Party will have an obligation to agree to any such proposed program, or proposed Sponsor Project Agreement or SOW.

**2.4** Steering Committee. Promptly after the Effective Date, the Parties shall form a committee (the "Steering Committee"), comprised of two representatives from each Party, appointed (and if applicable replaced) by each such Party. The Steering Committee shall meet (either in person or by teleconference or videoconference, reasonably agreed by the Parties) at least once per calendar quarter, or more often as needed to address matters needing resolution in the collaboration hereunder between the Parties or arising under the SOWs or Development work. All representatives on the Steering Committee shall work in good faith and reasonably to discuss and seek to find consensus on all matters raised at Steering Committee meetings and on all matters needed resolution or decision. All decisions made and actions taken by Steering Committee shall require unanimous agreement by the representatives on the Steering Committee. The Steering Committee shall have the responsibility to manage and oversee the Parties' efforts to identify possible Sponsors and negotiate and enter into Sponsor Project Agreements, the performance and activities under the Sponsor Project Agreements, each Party's conduct of the Development work under the SOWs, compliance with the timelines in the SOW, and the development and commercialization of PDP Assays, and such other appropriate matters arising under the Parties' collaboration under this Agreement. However, for clarity, the Steering Committee shall not have any authority to modify, amend, interpret or waive any terms or obligations under this Agreement.

## 3. CONDUCT & RESPONSIBILITIES REGARDING STATEMENTS OF WORK

**3.1** As this Agreement serves as the master agreement for the collaboration of the Parties for PDP Assay development in the Fields, the Parties agree that such Development efforts shall be conducted in accordance with SOWs agreed to by the Parties under this Article 3. With respect to each particular Project that the Parties agree to undertake, pursuant to the applicable Sponsor Project Agreement, to develop a PDP Assay in partnership with or in support of the applicable Sponsor, the Parties must agree to the SOW covering such Development activities pursuant to the below terms, before such Project can be officially committed and undertaken under such Sponsor Project Agreement.

**3.2** With respect to each Project, the parties shall (prior to QIAGEN committing to the Project under the applicable Sponsor Project Agreement) discuss and in good faith use commercially reasonable efforts to agree on the terms and conditions of, and enter into, an individual Statement of Work for such Project, and such SOW shall: (a) identify the Sponsor and the nature of the Project, describe in all reasonable detail the agreed upon Development plan for Development of the PDP Assay under such Project, including setting forth for each Party the specific agreed upon Development work to be performed by such Party in developing such PDP Assay, include any corresponding research protocols to be followed by HTG and clinical development protocols to be followed by QIAGEN, the budget for conducting such work, and set forth the compensation to be paid by QIAGEN to HTG with respect to such HTG's performance of such Development work and (if applicable) the amounts (out of payments by a Sponsor) to be retained by QIAGEN as compensation for its Development work. A template Statement of Work is attached hereto as Exhibit A (with the understanding that the Parties may vary from such template, as needed for any particular SOW). The Parties shall mutually discuss and in good faith use commercially reasonable efforts to agree in writing to each Statement of Work, and upon the execution of any such Statement of Work by the Parties, the Statement of Work shall be added to this Agreement as an exhibit, with each subsequent Statement of Work being numbered in sequential number (i.e. Exhibit A-1, A-2, A-3, etc.). HTG shall have no obligation to perform any Development work on any particular proposed Project until the Parties mutually agree on the terms and conditions of and enter into one or more Statement of Work covering such work, and the particular terms (including compensation) covering such

work. Each executed SOW shall be deemed incorporated into and made part of and governed by this Agreement.

**3.3** Upon the Parties entering into a particular Statement of Work, each of HTG and QIAGEN agrees to perform the Development work allocated to such Party under such SOW, in conformance with the terms and conditions of this Agreement, the corresponding Statement of Work, including without limitation, the applicable protocol(s) set forth in such SOW, and/or any other operating procedures and/or specifications set forth in a Statement of Work. To the extent any terms or conditions of a Statement of Work conflict with the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control unless otherwise specifically set forth in such Statement of Work. Any term or condition included in any purchase order issued by QIAGEN in connection with a Statement of Work, or in any acknowledgement, invoice, or similar document issued by either Party that conflicts with the terms and conditions of this Agreement and/or the applicable Statement of Work will not apply to or govern the transaction resulting from the Statement of Work, unless both Parties expressly agree in writing to the particular conflicting term or condition, in which event the agreed term or condition will apply only with respect to that particular Statement of Work.

**3.4** Each Party shall perform the Development work allocated to it in an SOW using its own independent professional judgment in accordance with the applicable provisions of the Statement of Work, including without limitation, the applicable protocol(s) and/or any other operating procedures and/or specifications set forth in the Statement of Work, in a timely and professional manner and in conformity with the highest applicable industry standards, Applicable Laws, regulations and guidelines for the conduct of clinical research and governing protections of human subjects (to the extent applicable to such work), including but not limited to, ICH GCP, 21 C.F.R. Part 50 and 21 C.F.R. Part 312.50, and such other standards of good clinical practice as are required by the U.S. Food and Drug Administration ("FDA") and/or other regulatory authorities, and all applicable privacy and data protection laws, rules and regulations. The Development work of a Party shall be performed under the direction and supervision of such Party's employee identified in the corresponding Statement of Work (the "Project Lead", as to such SOW and the related Project).

**3.5** Neither Party shall subcontract, delegate or otherwise assign (except as permitted in Section 15.4) the performance of any of its Development work or any other of its obligations and responsibilities under this Agreement without the prior written approval of the other Party, such approval not to be unreasonably withheld, refused or delayed, or except as expressly contemplated in the applicable SOW. If a Party has such approval, such Party shall be solely responsible for ensuring that its agreements with its subcontractors are consistent with the terms of this Agreement, and such Party acknowledges and agrees that any such agreements with its subcontractors must permit the other Party to audit and assess such subcontractors and/or their respective facilities and personnel as provided for in this Agreement. A Party's approval of the use by the other Party of any subcontractor does not relieve the other Party of any of its obligations and responsibilities hereunder, and such other Party will at all times remain primarily liable for the performance of its obligations responsibilities under this Agreement and/or the corresponding Statement of Work. Any breach or violation of this Agreement and/or a corresponding Statement of Work by the subcontractor of a Party shall automatically be deemed a breach or violation by such Party of this Agreement and/or the corresponding Statement of Work.

**3.6** Any agreed upon change or modification to this Agreement and/or a Statement of Work shall be set forth in writing and signed by an authorized representative of the Parties (a "Change Order"). No such

change or modification shall be effective unless and until a Change Order is signed by an authorized representative of the Parties.

**3.7** Each Party's Project Lead shall keep the other Party, and (if applicable) the relevant Sponsor, updated and consult with such other Party on a reasonably regular basis with respect to all the Development work being conducted by such Party, with respect to each corresponding Statement of Work. In addition, within sixty (60) days after execution of a Statement of Work, the Parties will form a joint Project team (the "Joint Project Team" or "JPT"), which shall be responsible to facilitate the operational tasks and provide updates on the status and progress of the Development work being conducted under the Statement of Work. In the event either party becomes aware that a delay in the Development work is likely to occur, that party shall promptly notify the other party so that the parties, through the JPT, can attempt to mitigate or prevent the delay. Each such JPT shall meet via telephone or video conferences, on a regular basis, however, at least once per month, until the work conducted under the applicable SOW is completed. Each JPT shall be composed of not more than three (3) representatives appointed by each Party, with such representatives having appropriate experience and responsibility for the work under the applicable SOW. Each representative of a Party shall be appointed (and may be replaced at any time) by such Party upon prior written notice to the other Party. These representatives shall have appropriate experience, knowledge, and ongoing familiarity with the particular Project in their then current phases. One (1) representative of HTG and one (1) representative of QIAGEN shall be designated as the co-chairs of the JPT (together the "JPT Chairs"). All members designated by a Party shall have one (1) collective vote, to be cast by such Party's JPT Chair, on all matters before, or decided by, the JPT. Except as otherwise provided herein, all decisions of the JPT shall be made unanimously and the JPT members shall use reasonable, good faith efforts to reach agreement on all matters within its Statement of Work. If the JPT is unable to agree on any matter after good faith attempts to resolve such disagreement, then the JPT Chairs shall, refer the disagreement to a meeting between the Vice President, Business Development of QIAGEN and the Chief Executive Officer of HTG ("Executive Meeting"), which meeting shall take place as soon as practicable, but in no event later than seven (7) days after the date of the relevant referral.

**3.8** Each Party shall generate, shall implement appropriate measures to generate, complete and accurate records of all Development work undertaken and all results and Inventions made while performing the Development work under each SOW (collectively, "Records"), and shall ensure that all Records are appropriately recorded in specific notebooks or electronic files and are archived appropriately, during the performance of the Development work and upon the expiration or termination of this Agreement. Records that are archived to durable media shall be refreshed at appropriate intervals to mitigate risk of data loss due to media degradation. Each Party shall disclose, on a regular basis, its Records to the other Party as needed for the other Party to conduct the respective Project.

**3.9** Delays in Meeting Deadlines. In the event that: (i) HTG provides QIAGEN with notice of expected delay in performing the Development work under a Statement of Work and HTG fails to provide prompt, reasonable assurance that it can mitigate or cure such delay to QIAGEN' s reasonable satisfaction; (ii) HTG gives QIAGEN reason to believe with substantial certainty that HTG will fail to meet an impending deadline and HTG fails to provide prompt, reasonable assurance upon request by QIAGEN; or (iii) HTG actually fails to meet a deadline expressly set forth in the Statement of Work, and the delay is likely to result in a failure to meet a deadline assigned by the Sponsor in the Sponsor Project

Agreement (each a "Project Delay"), then the Project Delay shall be immediately referred to the JPT and the Parties shall conduct informal resolution of the matter(s) as provided in Section 3.7. [***…] If the Parties are unable to resolve the Project Delay in a manner that would avoid a failure to meet a deadline assigned by the Sponsor, and Sponsor is unwilling to excuse the Project Delay, QIAGEN shall have the right, but not the obligation, to terminate the relevant Statement of Work. The Parties understand and agree that in some cases, the Sponsor may demand alternative remedies in the event of a Project Delay that cannot be cured within a reasonable period of time. Such remedies may include, by way of example, [***…] for completion of activities in a Project by Sponsor or its delegate. Any such […***…] shall be considered a "Key Term" requiring HTG's consent prior to QIAGEN agreeing to such term in the Project Sponsor Agreement. For clarification, any such delay shall be excused to the extent it has been directly caused by a QIAGEN Failure. For purposes of this Agreement, a "QIAGEN Failure" means any failure or delay by QIAGEN to meet any deadlines or perform any obligations explicitly assigned to QIAGEN in a Statement of Work.

## 4. POSSIBLE TRANSFER OF MATERIALS

**4.1** Though it is not contemplated that PDP Assay development by HTG will require access to QIAGEN Materials, if a particular Project requires such access and the applicable SOW contemplates that QIAGEN will make such QIAGEN Materials available to HTG for such work, then QIAGEN shall use reasonable efforts to transfer applicable QIAGEN Materials to HTG solely for use in the performance of the Development work of HTG under such SOWs, in strict accordance with the terms and conditions of this Agreement and/or the corresponding Statement of Work. Accordingly, QIAGEN hereby grants to HTG, during the Term and subject to the terms and conditions set forth herein, a limited, nonexclusive, non-sublicensable, nontransferable (except as may be otherwise agreed to by the Parties in writing), royalty-free license to use the QIAGEN Materials for the sole purpose of performing the Development work to be performed pursuant to the applicable Statement of Work. HTG shall: (i) use reasonable efforts to comply with all Applicable Laws relating to the QIAGEN Materials in performing its obligations and responsibilities under the applicable Statement of Work; (ii) use the QIAGEN Materials solely in connection with conducting the specific activities under the applicable Statement of Work and for no other purpose; and (iii) at all times retain possession of the QIAGEN Materials and not provide or transfer any part of the QIAGEN Materials to any third party without QIAGEN's prior written consent. HTG acknowledges that nothing in this Agreement grants HTG any rights to use the QIAGEN Materials for any purpose other than in connection with the performance of the Development work under an SOW.

**4.2** Except as otherwise set forth in a Statement of Work, QIAGEN shall be solely responsible for shipping and/or transporting the QIAGEN Materials to HTG. QIAGEN shall bear all risk of loss or damage to the QIAGEN Materials up to their delivery to HTG. QIAGEN shall provide HTG all information in its possession regarding safety precautions for, and hazards of, any QIAGEN Materials transferred to HTG.

**4.3** HTG shall, following their delivery by QIAGEN, use commercially reasonable efforts for the appropriate storage of the Materials in compliance with Applicable Laws. In particular, HTG shall, following their delivery by QIAGEN, use commercially reasonable efforts to store and maintain the Materials, to the extent applicable, in accordance with Applicable Laws and current best practices with respect to the storage and maintenance of human samples.

## 5. FINANCIAL TERMS

**5.1** QIAGEN shall pay HTG for the Development work performed by (or on behalf of) HTG under this Agreement in accordance with the fees, timelines, payment terms and budget included with each Statement of Work. Potential compensation arrangements will depend on the development and/or commercialization activities of the Parties, and shall be commercially reasonable as agreed by the Parties in good faith, and may include:

**5.1.1** Up-front payments as partial, advance payment for milestones;

**5.1.2** Milestone payments upon the achievement of milestones within the applicable SOW; or

**5.1.3** Any other arrangement mutually agreed by the Parties.

**5.2** The Parties further agree that, HTG shall be entitled to a share (according to the below schedule) of Net Profits resulting from the conduct of a particular SOW, as follows:

**5.2.1** For development of PDP Assays that are primarily based on HTG IP, HTG shall receive 50% of the Net Profits resulting from the SOW, taking into account and including all payments by the applicable Sponsor to QIAGEN in connection with the SOW;

**5.2.2** For development of PDP Assays that are primarily based on QIAGEN IP, HTG shall receive 20% of the Net Profits resulting from the SOW, taking into account and including all payments by the applicable Sponsor to QIAGEN in connection with the SOW;

**5.2.3** For sales or other commercial transfer of HTG or QIAGEN instruments, tools or other products (excluding any PDP Assay) to the Sponsor or its Affiliate or contractor, in connection with an SOW or Project, the Parties shall share equally (50/50) all net revenue received by either Party for such sales, with "net revenue" equal to: (i) the net sales resulting from such sale or transfer (total amounts received, less typical, standard deductions actually incurred for such sale or transfer (such as for taxes, returns, etc), less (ii) the Cost of Goods for the product sold or transferred.

**5.2.4** On a calendar quarter basis, within 30 days after the end of each such quarter, the Parties shall meet and review all applicable books of account and determine, for such quarter ended, what are the to-date Net Profits and net revenues through the end of such quarter and shall, to the extent not previously shared between the Parties under the above provisions, allocate and share such amounts per the above sharing percentages. For example, if a Development milestone is met, under a particular Project, and the Sponsor has paid in a particular quarter a milestone payment for having achieved such milestone, then per the above the Parties will determine what amount of such milestone payment is Net Profit, by deducting the Development payment amounts owed to each Party for its Development work conducted up to meeting the milestone, and then the remaining Net Profit shall be distributed (according to the above percentages) to each Party by QIAGEN, within 10 days of such determination.

**5.3** Compensation to HTG shall be invoiced and paid in U.S. Dollars ("USD").

**5.4** Financial Records and Audits. Each Party shall keep full, true, and accurate books of account regarding the Development work conducted by (or on behalf of) such Party hereunder and of all revenues, costs and expenses received or incurred in relation to SOWs or the conduct thereof under each applicable Sponsor Project Agreement, as needed to calculate amounts reimbursable hereunder or the Net Profits or net revenues (as contemplated in Section 5.2) resulting from each SOW, for at least seven years after the creation of such records. Such records shall include all particulars reasonably necessary for the purpose of supporting the charges for Development work provided under this Agreement and the calculation of Net Profit and net revenues. At the expense of the Party, except as specified below, each Party has the right during the term to engage an independent public accountant to perform, on behalf of such Party, an audit, conducted in accordance with United States Generally Accepted Accounting Principles (US GAAP), of such books and records of the other Party reasonably necessary for the independent public accountant to support the charges for the audited Party's Development work, or the amount of Net Profits or net revenues (as applicable). Any such audit shall be conducted upon at least thirty (30) days' prior written notice from the auditing Party to the other Party and shall be conducted during regular business hours in such a manner as to not unnecessarily interfere with the auditing Party's normal business activities. Such audit shall not be performed more frequently than once per calendar year nor more frequently than once with respect to records covering any specific period of time. All information, data, documents and abstracts herein referred to shall be used only for the purpose of verifying the specific amounts (cost of Development work, or Net Profits, as applicable) consistent with the terms of this Agreement and shall be treated as the Confidential Information of the audited Party and subject to the confidentiality obligations of this Agreement. As a condition to such audit, such auditor shall have executed a confidentiality agreement reasonably acceptable to the audited Party regarding non-disclosure, non-use, and safeguarding of such information, data, documents and abstracts. Audit results shall be shared by QIAGEN and HTG. If the audit reveals that the audited Party has not complied with the applicable financial provisions of this Agreement, the audited Party shall compensate the other Party, within thirty (30) days of the audit report, for any amounts needed to come into compliance, and if such compensation exceeds 5% of the amount actually owed, then the audited Party also will reimburse the other Party for the reasonable fees of the accountant that performed the audit.

## 6. CONFIDENTIAL INFORMATION

**6.1** Each Receiving Party acknowledges and agrees that it may have access to and/or receive the Disclosing Party's Confidential Information during the Term of this Agreement. Each Receiving Party agrees to: (i) maintain the Disclosing Party's Confidential Information in strict confidence; and (ii) not use the Disclosing Party's Confidential Information or otherwise disclose such Confidential Information to any third party, except as authorized in this Agreement or as otherwise authorized by the Disclosing Party in writing. For clarification, QIAGEN may disclose particular HTG Confidential Information relating directly to a Project in strict confidence to the Sponsor identified in a Statement of Work for that Project, solely for Sponsor's internal business use in connection with its development of the Sponsor therapeutic that is the subject of such Project, and for no other use or purpose. Each Sponsor shall be under appropriate confidentiality and limited use obligations, with respect to each Party's Confidential Information, under terms of the applicable Sponsor Project Agreement.

**6.2** Each Receiving Party will store the Disclosing Party's Confidential Information in a secure location, and will handle and protect the Disclosing Party's Confidential Information with no less care than that with which it handles and protects its own highly confidential and proprietary information (but in no event less than a reasonable degree of care) to prevent the unauthorized use, publication or disclosure of the Disclosing Party's Confidential Information.

**6.3** Each Receiving Party may only disclose the Disclosing Party's Confidential Information: (i) with the prior written consent of the Disclosing Party; or (ii) to the Receiving Party's employees, directors, agents, and/or professional advisors, and those of its Affiliates ("Representatives") having a bona fide need to know the Disclosing Party's Confidential Information for purposes of performing the Receiving Party's obligations and responsibilities under this Agreement and/or a Statement of Work and who are likewise bound by written agreements with the Receiving Party including confidentiality and non-use terms no less onerous than those set forth herein.

**6.4** The confidentiality and non-use obligations set forth in this Section 6 shall survive for the earlier of: (i) ten (10) years from the expiration or termination of this Agreement (except to the extent such Confidential Information includes the Disclosing Party's trade secrets, in which case the below Section 6.5 (ii) shall apply); or (ii) until the applicable portion of the Disclosing Party's Confidential Information becomes public; provided, that such Confidential Information does not become public as a result of a breach of this Agreement.

**6.5** A Receiving Party's obligations and responsibilities with respect to the Disclosing Party's Confidential Information as set forth in this Section 6 do not apply to particular information:

**6.5.1** That was known to the Receiving Party at the time it was obtained from the Disclosing Party, other than as a result of the Receiving Party's breach of any contractual obligation as shown by written evidence;

**6.5.2** That is acquired by the Receiving Party from a third party that is not under a contractual or other obligation not to disclose it;

**6.5.3** That is or becomes generally known or otherwise enters the public domain other than by the fault or omission of the Receiving Party; or

**6.5.4** That is independently developed by or on behalf of the Receiving Party without any use of any Confidential Information of the Disclosing Party.

**6.6** Notwithstanding the above obligations, a Receiving Party may disclose particular Confidential Information of Disclosing Party to the extent such disclosure is required by compulsory judicial or administrative process or by law or regulation, provided that the Receiving Party first provides prompt written notice of such disclosure to the Disclosing Party and, to the extent reasonably feasible under the circumstances, cooperates with the Disclosing Party's reasonable and lawful actions to avoid and/or minimize the extent of such disclosure.

**6.7** Upon the expiration or termination of this Agreement, or at any time upon request of the Disclosing Party, the Receiving Party will promptly return or destroy (at the Receiving Party's option) all items and materials, including any copies, in its possession, custody, or control that contain any of the Disclosing Party's Confidential Information. All notes or other work product containing the Disclosing Party's Confidential Information will be destroyed or archived with Receiving Party's other confidential records, and upon written request of the Disclosing Party, such destruction or archival will be certified in writing to the Disclosing Party by an authorized representative of the Receiving Party who supervised such destruction or archival. Notwithstanding this Section 6.7, the Receiving Party shall be entitled to retain one (1) archive copy of the Disclosing Party's Confidential Information solely for purposes of demonstrating its compliance with the terms and conditions of this Agreement. The Receiving Party's obligations of non-use and confidentiality set forth in this Section 6.7 shall continue to apply to any such retained Confidential Information for the period set forth in Section 6.4 above.

**6.8** The terms of this Agreement will be treated as the Confidential Information of the Parties pursuant to this Article 6, except that either Party may disclose the terms of this Agreement pursuant to litigation between the Parties to enforce, defend or interpret this Agreement. Further, either Party may disclose such terms: (a) as, and only to the extent, required by Applicable Laws as determined by competent legal counsel advising the Disclosing Party; (b) to its directors; (c) in confidence to bona fide potential acquirors or merger or strategic partners and their respective strategic professional advisors, all solely for diligence review in connection with a potential transaction with HTG and who are likewise bound by written agreements with or other professional duty to the Receiving Party including confidentiality and non-use terms no less onerous than those set forth herein.

**6.9** Without limiting the generality of any other provision hereof, neither Party shall publish (including without limitation, publishing articles and making presentations of any kind whatsoever) any confidential information regarding the Development work and/or any Sponsor's clinical study, directly or indirectly, without the prior written consent of the other Party and shall not assist any third party in the preparation of any such publishing without the prior written consent of the other Party.

## 7. OWNERSHIP; INTELLECTUAL PROPERTY

**7.1** As between the Parties, the HTG Property is and shall at all times remain the sole and exclusive property of HTG. As between the Parties, the QIAGEN Property is and shall at all times remain the sole and exclusive property of QIAGEN. Except as expressly provided for in this Agreement, no right or license, either express or implied, is granted by either Party to the other under any Intellectual Property Right or by virtue of the disclosure of any QIAGEN Property and/or HTG Property (as applicable) to the other Party under this Agreement, or otherwise. If HTG (or its Affiliates) invents, creates or develops any QIAGEN IP, HTG hereby assigns and agrees to assign to QIAGEN all its rights, title and interest in and to such QIAGEN IP. IF QIAGEN (or its Affiliate) invents, creates or develops any HTG IP, QIAGEN hereby assigns and agrees to assign to HTG all its rights, title and interest in and to such HTG IP.

**7.2** Each Party shall use reasonable efforts to indicate, in a summary manner in the relevant Statement of Work, any QIAGEN IP or HTG IP (as the case may be) that it believes in good faith is likely to be utilized in the conduct of the Development work for a particular Project. The Statement of Work shall contain (a) any licenses to any needed IP that shall be granted for purposes of performing the Development work under such SOW relating to the applicable Project and for HTG's performing of applicable manufacturing as contemplated in Section 8.3, and (b) a license to HTG IP as necessary for QIAGEN to complete any development, manufacture or commercialization of HTG-developed PDP Assays in the event of HTG's bankruptcy or insolvency during the term of the SOW, subject to applicable law.

**7.3** Except for any improvements, modifications or enhancements related to the HTG IP or QIAGEN IP, the Parties shall jointly own any Intellectual Property Rights generated by either Party pursuant to a Statement of Work that are related directly and specifically to biomarker selection for the applicable PDP Assay.

**7.4** Upon request by a Party, the other Party will do all lawful acts, including, but not limited to, the execution of papers and lawful oaths and the giving of testimony, that may be necessary or desirable in the determination of the other Party to secure and/or perfect such Party's Intellectual Property Rights as set forth in this Article 7.

## 8. REGULATORY, COMMERCIALIZATION AND BRANDING

**8.1** As between the Parties, with respect to regulatory approval matters for each HTG-developed PDP Assay, HTG shall be considered, the contract manufacturer for QIAGEN, and QIAGEN shall be considered the Legal Manufacturer of the PDP Assay. The Parties shall in good faith negotiate and use

commercially reasonable efforts to enter into a Quality Agreement with respect to the manufacture of a HTG-developed PDP Assay upon reasonable request by QIAGEN. For the avoidance of doubt, such Quality Agreement shall include guidelines and terms acceptable for QIAGEN's regulatory and quality departments including without limitation pre-meetings and regular update meetings to review and confirm product quality, documentation needs and timelines. QIAGEN shall have the right to utilize any of its Affiliates in the performance of its manufacturing and commercialization obligations under this Agreement.

**8.2** QIAGEN shall have responsibility for obtaining any regulatory approvals that may be required or appropriate for the marketing and sale of each PDP Assay in all jurisdictions throughout the Territory, unless otherwise agreed in a Statement of Work

**8.3** QIAGEN shall have the sole rights and responsibility, using its commercially reasonable efforts, for the marketing, promotion, distribution and sale of each PDP Assay in all jurisdictions throughout the Territory, solely for use in the PDP Field. For HTG-developed PDP Assays, QIAGEN shall purchase such HTG-developed PDP Assays, at the transfer price established in the applicable SOW, pursuant to a Supply Agreement containing typical and commercially reasonable supply provisions, to be negotiated in good faith and entered into by the Parties at the appropriate time (prior to commercialization of a HTG-developed PDP Assay). The transfer price shall be based on a "cost of goods sold plus mark-up" model, whereby the actual expectation of HTG for the mark-up is estimated to be [***…]%. Subject to any limitations in such Supply Agreement, it shall include, without limitation: (i) an obligation by HTG to supply the HTG-developed PDP Assay for as long as QIAGEN wishes to purchase such HTG-developed PDP Assay from HTG, and (ii) an indemnification from HTG to QIAGEN for any third party claims for defective design or manufacture of such HTG-developed PDP Assay by HTG. For QIAGEN-developed PDP Assays, QIAGEN shall pay a royalty on the sale of each such PDP Assay, at a rate established in good faith in the applicable SOW.

**8.4** Each PDP Assay shall be sold under the QIAGEN brand name; however, the Parties may also agree in a particular Statement of Work to acknowledge HTG's technology or brand name in the marketing materials and product packaging for any particular PDP Assay.

## 9. INDEMNIFICATION

**9.1** HTG shall defend, indemnify and hold harmless QIAGEN, and its successors and assigns, and the officers, directors, employees, agents and representatives of the foregoing, (the "Qiagen Indemnitees") from and against, any and all damages, losses, liabilities, claims, fines, penalties and expenses (including costs of investigation and defense and reasonable attorneys' fees) (collectively, "Damages") arising from any and all claims, proceedings, actions, arbitrations, hearings, investigations and suits ("Claims") brought by any third party against a Qiagen Indemnitee to the extent such Claims result from or arise out of: (i) HTG's material breach of this Agreement, including, with the exclusion of Section 10.1, a breach by HTG of its representations and warranties set forth in Section 10 below; (ii) the material failure on the part of HTG to comply with Applicable Laws; or (iii) the gross negligence or willful misconduct by HTG, its agents, employees or representatives, *provided,* however, that in no event shall HTG be obligated to indemnify, defend or hold harmless any Qiagen Indemnitees, for, from or against any Damages or Claims to the extent related to or arising from any subject matter or occurrence for which QIAGEN shall have the obligation to indemnify HTG under Section 9.2 below if such subject matter or occurrence were to give rise to a Claim against an HTG Indemnitee (as defined below).

**9.2** QIAGEN shall defend, indemnify and hold harmless HTG and its successors and assigns, and the officers, directors, employees, agents and representatives of the foregoing, (the "HTG Indemnitees") from and against any and all Damages arising from any Claims against any HTG Indemnitee resulting from or arising out: (i) QIAGEN's material breach of this Agreement, including without limitation, a breach by QIAGEN of its representations and warranties set forth in Section 10 below; (ii) the material failure on the part of QIAGEN to comply with Applicable Laws; (iii) the gross negligence or willful misconduct conduct by QIAGEN or its Affiliate or their respective agents, employees or representatives; or (iv) claims for personal injury and/or death resulting from a defective design or manufacture of the QIAGEN Property.

**9.3** A Party (the "Indemnified Party") that asserts that it (or its related party) is owed an indemnity hereunder by the other Party (the "Indemnifying Party") shall promptly notify the Indemnifying Party of the Claim for which such indemnity is believed to be owed and shall provide with such notice all information about such Claim and its basis that Indemnified Party is aware, provided that, the failure of the Indemnified Party to promptly notify the Indemnifying Party of the Claim will not relieve the Indemnifying Party of its duties under this Article 9 except to the extent that the Indemnifying Party is materially prejudiced by the delay. Provided that the Indemnifying Party undertakes and continues to prosecute in good faith the defense of such Claim, the Indemnified Party shall have no right to tender an appearance in the proceedings around such Claim. Upon undertaking such defense, the Indemnifying Party shall have full control over all the proceedings and filings involved in the defense of the Claim, including selection of counsel to tender appearance for the Indemnifying Party and for the Indemnified Party. The Indemnified Party and all applicable indemnitees thereof shall provide full cooperation in the defense against such Claim, including promptly signing any and all reasonably necessary documents relating to such defense, including for the selection of counsel, such as a joint defense agreement, and providing all other assistance and support including access to witnesses, documents and materials and appearing in hearings or defense meetings, and shall not unreasonably withhold its consent to conflict waivers. The Indemnified Party's attorney's fees shall be limited to those necessary for complying with the Indemnifying Party's requests for support that necessarily call for the use of the Indemnified Party's counsel (*e.g.,* preparing a witness for deposition). The Party seeking indemnification hereunder (and its related indemnitee) shall not unreasonably withhold its approval of the settlement of any Claim covered by Section 9.1 or 9.2, as applicable, will cooperate with counsel of the Indemnifying Party, and reserves the right to engage its own counsel to assist in the defense at the expense of the indemnifying party.

## 10. COVENANTS; REPRESENTATIONS AND WARRANTIES

**10.1** HTG represents and warrants to QIAGEN that, as of the Effective Date, is has not entered into any contract or otherwise agreed to terms with a third party that would prohibit, conflict with or otherwise restrict HTG's ability to enter into this Agreement on the terms and conditions herein.

**10.2** With regard to debarment and related matters:

**10.2.1** Each Party represents and warrants to the other Party that, as of the Effective Date, the representing Party has not, nor to its knowledge, have any of its employees or agents who may perform Development work pursuant to this Agreement, ever been, currently, or are the subject of a proceeding that could lead to it/them becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted

Entity or Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List.

**10.2.2** Each Party agrees that if, during the Term of this Agreement, it becomes, or to its knowledge, any of its employees or agents working on its behalf, become or are the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or added to FDA's Disqualified/Restricted List, the affected Party shall immediately notify the other Party, and the other Party shall have the right to immediately terminate any affected Statement of Work or, if all Statements of Work are affected, terminate this Agreement.

**10.2.3** For purposes of this section, the following definitions shall apply:

**10.2.3.1** A "Debarred Individual" is an individual who has been debarred pursuant to 21 U.S.C. § 335a (a) or (b).

**10.2.3.2** "Debarred Entity" is a corporation, partnership or association that has been debarred pursuant to 21 U.S.C. § 335a (a) or (b).

**10.2.3.3** An "Excluded Individual" or "Excluded Entity" is: (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services pursuant to section 1128 of the Social Security Act (42 U.S.C. § 1320a-7(b)); or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

**10.2.3.4** A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

**10.2.3.5** "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics or devices pursuant to 21 C.F.R. Part 312.70.neither HTG nor any of its employees or agents

**10.3** Each Party represents and warrants to the other that: (i) it is and will be at all times during the Term a valid legal entity existing under the law of its state of incorporation with the power to own all of its properties and assets and to carry on its business as it is currently being conducted; and (ii) the execution and delivery of this Agreement has been duly authorized and no further approval, corporate or otherwise, is required in order to execute this binding Agreement.

**10.4** QIAGEN represents and warrants to HTG that: (i) it owns the QIAGEN Materials or otherwise has all necessary rights to license and/or transfer the QIAGEN Materials, or any other specimens or samples to HTG for the purposes contemplated herein and to otherwise grant the rights granted to HTG hereunder; (ii) QIAGEN and/or Sponsor has, in obtaining and maintaining the QIAGEN Materials or any other specimens or samples, complied with all Applicable Laws; (iii) QIAGEN has, or the Sponsor has, obtained all necessary favourable opinions from the relevant research ethics committees and all authorizations, consents and documentation from the relevant regulatory authorities required to conduct the Study; and (iv) QIAGEN and/or the Sponsor shall be solely responsible for the authorization and conduct of each clinical trial or study conducted in connection with a Project or SOW, and will comply with ICH GCP, FDA regulations 21 C.F.R. 50 and 21 C.F.R. 312.50, or equivalent international standards, and such other standards of good clinical practice as are required by the FDA or such other regulatory authorities with jurisdiction where the Samples will be used in the Study, and all applicable privacy and data protection laws, rules and regulations.

**10.5** In the performance of its obligations under any Statement of Work, each Party shall assign qualified personnel to perform the Development work in a professional and workmanlike manner in accordance with current industry standards.

**10.6** NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY NOT EXPRESSLY SET FORTH ABOVE IN THIS SECTION 10, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR ARISING FROM COURSE OF TRADE, COURSE OF DEALING OR OTHERWISE, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, USAGE, VALIDITY, AND/OR NON-INFRINGEMENT.

## 11. LIMITATION OF LIABILITY AND INSURANCE

**11.1** EXCEPT FOR DAMAGES RESULTING FROM A BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE 6 ABOVE, IN NO EVENT WILL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL OR PUNITIVE DAMAGES, INCLUDING ANY DAMAGES FOR BUSINESS INTERRUPTION, LOSS OF USE, DATA, REVENUE OR PROFIT, WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT THE PARTY ALLEGED TO BE LIABLE WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. FOR CLARITY, THIS SECTION 11.1 SHALL NOT LIMIT A PARTY'S INDEMNITY OBLIGATIONS UNDER ARTICLE 10.

**11.2** Insurance. During the term of this Agreement, each Party shall maintain the following insurance:

**11.2.1** General Liability with limits of not less than USD $2,000,000 per occurrence or claim and in the aggregate including coverage for personal injury and property damage;

**11.2.2** Workers Compensation as required by local statutory requirements;

**11.2.3** Auto Liability with limits of not less than USD $1,000,000 per occurrence or claim; and

**11.2.4** Umbrella Liability insurance with limits of not less than USD $5,000,000. Coverage shall be in excess of the above captioned general liability and auto liability insurance coverage.

## 12. AUDIT AND RECORD RETENTION

**12.1** During the Term, each Party, may upon good cause shown and on reasonable prior notice to the other Party, at a mutually agreeable time during the other Party's normal business hours, but no more than once per calendar quarter, assess such other Party's facilities and materials actually used in conducting its Development work hereunder, which may include applicable equipment, tools, processes, Project related output, and personnel, solely as necessary in order to assess the other Party's performance of its Development work under this Agreement. All information and materials of the audited Party shall be deemed, and treated by auditing Party as, the Confidential Information of audited Party.

**12.2** Each Party will notify the other promptly (within five (5) business days) in the event of any actual or notified inspection by a regulatory or administrative authority of such Party's facilities where Development work are being performed. Each Party will promptly provide the other with copies of any correspondence from or to the regulatory authorities such as the FDA, related to any such inspection, including but not limited to any FDA 483s or warning letters, as well as any other correspondence with a governmental agency, in each case solely to the extent that is reasonably likely that such actions will affect the suitability of such Party to continue performing the applicable Development work. In such event, the Party will consult with and allow the other Party and/or the applicable Sponsor (if permitted under the applicable Sponsor Project Agreement) to review and comment on any responses made by such Party to the regulatory and/or governmental authority relating to such inspection in advance of such responses being submitted.

**12.3** Each Party will ensure that its Project Lead and his or her personnel host and/or attend any such regulatory or governmental audit or inspection, and further assist in the preparation therefor and fully cooperate with the respective regulatory and/or administrative authority, the other Party, Sponsor (if applicable, and permitted by the applicable Sponsor Project Agreement) and/or its or their representatives. All personnel time and resources necessary to complete such an audit shall be provided by the audited party on a time and materials basis, to be reimbursed by the other party unless the audit demonstrates that the audited party has materially breached its obligations under this Agreement with respect to its Development work obligations, in which case, the audited party shall bear all cost and expense for such audit.

**12.4** Each Party shall use commercially reasonable efforts to promptly remedy, at its own cost and expense, with competent proof, any audit findings made by any regulatory or administrative authority, the other Party, Sponsor (if applicable) and/or its or their representatives that relate to defects in such Party's facilities where the Development work is being performed, the Party's Development work, and/or such Party's non-compliance with this Agreement and/or Applicable Laws.

## 13. TERM AND TERMINATION; LOSS OF EXCLUSIVITY

**13.1** This Agreement shall commence as of the Effective Date and shall continue for a period of five (5) years thereafter, unless sooner terminated under this Article 13 (the "Term").

**13.2** QIAGEN shall have the right to suspend or terminate, as applicable, a Statement of Work if the relevant Project is suspended or terminated by the applicable Sponsor. HTG shall cooperate with and support QIAGEN in the management of such suspension, including maintaining resources and materials for a reasonable period of time to enable a timely re-start. The Parties may agree to specific terms for Project suspensions in the relevant Statement of Work.

**13.3** Change of Control.

**13.3.1** In the event that either Party undergoes a Change of Control during the Term, it shall provide written notice of such Change of Control to the other Party at least seven (7) days prior to the expected closing of the Change of Control transaction.

**13.3.2** Either Party shall have the right to terminate this Agreement and any or all Statements of Work in the event of a Change of Control of itself or the other Party.

**13.3.2.1** In the event a Party terminates this Agreement in the event of a Change of Control of itself, it shall provide notice to the other Party within thirty (30) days after the closing of the Change of Control transaction and make a payment of USD $2,000,000 to the other Party within such 30-day notice period.

**13.3.2.2** In the event a Party wishes to terminate this Agreement in the event of a Change of Control involving the other Party, it shall provide notice to the other Party within the later of (i) forty-five (45) days of its receipt of the notice described in Section 13.3.1 regarding the Change of Control and (ii) thirty (30) days after the closing of the Change of Control.

**13.4** All Fields, including the Oncology Field, shall become non-exclusive in the same manner as the Fields described in Section 2.3.2, 60 days following receipt of written notice by one Party to the other Party citing this section, in the event that:

**13.4.1** the Parties have not signed at least [***…] SOW pursuant to a Sponsor Project Agreement by the first anniversary of the Effective Date; or

**13.4.2** the Parties have not signed, pursuant to a Sponsor Project Agreement, an aggregate of (i) at least […***…] SOWs or Project Sponsor Agreements with gross proceeds of at least USD $[…***…] by the second anniversary of the Effective Date, or (ii) at least […***…] SOWs or Project Sponsor Agreements with gross proceeds of at least USD $[…***…] or more by the third anniversary of the Effective Date.

**13.5** This Agreement and/or a Statement of Work may be terminated by either Party, as follows:

**13.5.1** Either Party may terminate this Agreement in the event the other Party materially breaches the terms of this Agreement and, provided that the non-breaching Party shall have given the breaching Party written notice of such breach, setting forth the details of the breach, and the breaching Party shall have not cured such breach within thirty (30) days after receipt of such notice; or

**13.5.2** Either Party may terminate a Statement of Work in the event the other Party materially breaches the terms of such Statement of Work and, provided that the non-breaching Party shall have given the breaching Party written notice of such breach, setting forth the details of the breach, and the breaching Party shall have not cured such breach within thirty (30) days after receipt of such notice; or

**13.5.3** Either Party may terminate the applicable Statement(s) of Work or, if all Statements of Work are affected, this Agreement, upon written notice to the other, in the event the performance of one or more Statements of Work by a Party is prevented or delayed by reason of (a) a force majeure event affecting a material obligation that persists for more than sixty (60) consecutive days, or (b) inability to obtain, in a reasonable time, appropriate needed regulatory approvals in a country material to the Sponsor, or (c) there are intellectual property infringement or violation issues that have enjoined the sale of the applicable PDP Assay, or QIAGEN sequencing equipment, and such issues cannot be overcome by commercially reasonable efforts to the satisfaction of either Party; or

**13.5.4** A Party may terminate this Agreement, upon written notice to the other Party effective immediately, in the event the other Party enters bankruptcy proceedings, ceases to operate in the normal course of business, or generally fails to pay, or admits in writing its inability to pay its debts as they mature, or applies for, consents to, or acquiesces in the appointment of a trustee, receiver or other custodian for the other Party or for a substantial part of the property of the other Party, or makes a general assignment for the benefit of creditors, or in the absence of such application, consent or acquiescence, a trustee, receiver or other custodian is appointed for the other Party or for a substantial part of the property of the other Party, or any bankruptcy, reorganization, debt arrangement or other proceeding under any bankruptcy or insolvency law, or any dissolution or liquidation proceeding, is instituted by or against the other Party, or any warrant of attachment or similar legal process is issued against any substantial part of the property of the other Party.

**13.6 Consequences of Termination.** Upon the termination or expiration of this Agreement, the Parties shall have the following rights, obligations and responsibilities:

**13.6.1** The termination or expiration of this Agreement shall not automatically result in the termination of any then-active Statement of Work. In the event of the expiration of this Agreement and/or the termination by either Party of this Agreement pursuant to Section 13.5 above, any then-active Statement of Work shall continue in effect, unless earlier terminated, as permitted pursuant to this Section 13, for the duration of such Statement of Work and the terms of this Agreement shall survive only to the extent necessary to govern such Statement of Work until its completion or termination.

**13.6.2** Following HTG's receipt or giving of a termination notice or otherwise upon the expiration or termination a Statement of Work or this Agreement, HTG shall, within sixty (60) days thereof, invoice QIAGEN for all amounts owed for the Development work performed prior to the effective date of termination or expiration under this Agreement and/or the terminated Statement of Work, as applicable, for which HTG has not yet been paid. HTG shall additionally avoid, to the extent reasonably practicable, incurring

additional costs and expenses on Development work for the terminated SOW during the closeout or winding down period.

**13.6.3** Upon the termination or expiration of this Agreement and/or a Statement of Work, and except as otherwise set forth in Section 13.6.3, all rights and obligations of the Parties under this Agreement and/or the terminated or expired Statement of Work shall immediately and automatically cease. Upon the termination or expiration of this Agreement and/or a Statement of Work, each Party shall immediately deliver to the other, at the other Party's expense, all of the other Party's Confidential Information, and (if applicable) any remaining QIAGEN Materials in HTG's possession, that have not yet been delivered to such other Party as of the date of such expiration or termination. Within sixty (60) days after the expiration or earlier termination of a Statement of Work for any reason, HTG will further provide to QIAGEN a final report detailing all results obtained pursuant to its Development work under such Statement of Work.

**13.6.4** The expiration or termination of this Agreement and/or a Statement of Work for any reason or no reason will not release any Party from any obligation that matured prior to the effective date of such expiration or termination. Sections of this Agreement that by their nature prescribe continuing rights and obligations will survive until their purposes are fulfilled, including Section 6 (Confidential Information), Section 7 (Ownership; Intellectual Property), Section 9 (Indemnification), Section 11 (Limitation of Liability) Section 13.6 (Consequences of Termination), Section 14 (Non-Solicitation), and Section 15 (General Provisions).

## 14. NON-SOLICITATION

**14.1** During the Term, and for a period of two (2) years thereafter (provided that, in the event of a breach by either Party of any covenant set forth in this Section 14.1, the term of such restriction will be extended by the period of the duration of such breach) neither Party shall, on its own behalf or on behalf of any third party, directly solicit for employment any person who was an employee or independent contractor of the other Party during the Term of this Agreement, without the prior written consent of the other Party. For clarification, the foregoing shall not prohibit a party from employing any such person who (i) contacts the party on his or her own initiative without any direct solicitation by or encouragement from the party, (ii) ceases to be employed by the other party prior to any direct solicitation by or encouragement or (iii) responds to a general employment advertisement or other general solicitation or recruitment effort not specifically aimed at employees of the other party.

## 15. GENERAL PROVISIONS

**15.1 Notices.** All notices or other communications given hereunder shall be in writing, shall be signed by an officer of the Party sending such notice or other communication, and shall be delivered by hand, by overnight courier, by electronic mail or by facsimile (provided that the sending Party does not have reason to know that the electronic mail or facsimile was not received by the other Party), all delivery charges prepaid and addressed to the Parties as follows:

To HTG:

HTG Molecular Diagnostics, Inc..
Attn: Chief Executive Officer
3430 E. Global Loop
Tucson, AZ 85706

To QIAGEN:

QIAGEN Legal Department
19300 Germantown Road
Germantown, MD 20874

All such notices and communications will be effective on the date delivered, if in person, on the date of the postmark of that notice or communication if by courier. Either Party may change its address by giving notice of that change to the other Party.

**15.2 Waivers.** Neither Party will be deemed to have waived any of its rights under this Agreement until it has signed a written waiver of those rights, or except as provided by Applicable Law. Without limiting the preceding, no failure or delay by either Party in exercising any rights, powers or remedies under this Agreement will operate as a waiver of any such right, power or remedy, except as provided by Applicable Law, and no waiver will constitute a waiver of any other provision, breach, right or remedy, nor will any waiver constitute a continuing waiver or be effective except for the specific instance and for the specific purpose given.

**15.3 Amendments.** If either Party wishes to modify this Agreement or a Statement of Work, the Parties will confer in good faith to determine the desirability of such modification. No modification, change or amendment to this Agreement or an SOW will be effective until a written amendment is signed by both Parties.

**15.4 Assignment.** Neither Party shall have the right or ability to assign or transfer any interest in or delegate its obligations under this Agreement and/or a Statement of Work without the prior written approval of the other Party, which shall not be unreasonably withheld, *except that* each Party shall have the right, solely with notice to the non-assigning Party, to assign this Agreement to a successor in interest in connection with a merger or acquisition or sale of all or substantially all of the assigning Party's assets, subject to Section 13.3. This Agreement will be binding on and inure to a Party's permitted successors and assigns.

**15.5 Severability.** The terms and conditions of this Agreement are severable. If any term or condition of this Agreement is rendered invalid or unenforceable by any law or regulation, or declared null and void

by any court of competent jurisdiction, that part will be reformed, if possible, to conform to the law, and if reformation is not possible, that part will be deleted in such jurisdiction only and the remainder of the terms and conditions of this Agreement as well as the invalid or unenforceable term or condition in all jurisdictions where valid and enforceable will remain in full force and effect, unless enforcement of this Agreement without the invalid or unenforceable term or condition would be grossly inequitable under the circumstances or would frustrate the primary purpose of this Agreement.

**15.6 Remedies.** The Parties acknowledge and agree that a material breach of this Agreement by the other Party may result in immediate, irreparable and continuing damage to the non-breaching Party for which there will be no adequate remedy at law; and agree that in the event of any such material breach or violation or any threatened or intended breach or violation of this Agreement, the non-breaching Party, its successors and assigns, will be entitled to seek temporary, preliminary and permanent injunctive relief and/or restraining orders enjoining and restraining such breach or violation or such threatened or intended breach or violation and/or other equitable relief in addition to such other and further relief as provided for at law and in equity.

**15.7 Agreement to Arbitrate Disputes**

**15.7.1** Prior to arbitration, the Parties agree to and shall seek to conduct informal resolution of any issues or disputes that arise under this Agreement (a "Dispute"). Such informal process may be initiated with written notice of one Party to the other, describing the Dispute with reasonable particularity, and the other Party shall follow with a written response within ten (10) calendar days of receipt of such notice. Each Party shall promptly designate an executive with requisite authority to resolve the noticed Dispute. The informal procedure shall commence within 10 calendar days of the date of response. If the Dispute is not resolved within 30 business days of the date of commencement of the procedure, either Party may proceed to arbitration as set forth below to resolve the Dispute.

**15.7.2** The Parties agree that any Dispute between the Parties, and including any claim by either Party against any agent, employee, successor, or assign of the other Party, related to or arising under this Agreement, including any dispute or issue as to performance of a Party's obligations or breach of this Agreement or as to the validity or applicability of this arbitration clause, shall be resolved by binding arbitration administered by the American Arbitration Association under its Commercial Arbitration Rules, except as where those rules are intentionally varied by the Parties herein or pursuant to mutual written agreement. The parties expressly agree that the arbitration shall be conducted in Denver, CO, in the English language, and shall be governed by Delaware law. For good or equitable cause shown, the prevailing party shall be entitled to reimbursement of its reasonable attorney fees and arbitration costs by the other Party, according to the relative success on the merits, as assessed by the arbitrator(s) in such arbitration. The arbitration award shall be final, absent manifest error or fraud.

**15.7.3** The Parties are entering into this arbitration agreement in connection with a transaction involving interstate commerce. Accordingly, this arbitration agreement, and any proceedings

thereunder, shall be governed by the Federal Arbitration Act ("FAA") 9 USC 1-16. Any award by the arbitrator may be entered as a judgment in any court having jurisdiction.

**15.7.4** The foregoing agreement to arbitrate shall not restrict either Party's remedies or ability at any time to seek equitable relief for a breach or threatened breach of: (i) either Party's confidentiality obligations; or (ii) the misuse, misappropriation or infringement of either Party's Intellectual Property Rights.

**15.8 Independent Contractor; No Agency.** Neither Party will be deemed to be the employee, representative, agent, joint venturer or partner of the other Party for any purpose. Neither Party has the authority to obligate or bind the other, or to incur any liability on behalf of the other, nor to direct the employees of the other.

**15.9 Interpretation.** Both Parties have had the opportunity to have this Agreement reviewed by their attorneys. Therefore, no rule of construction or interpretation that favors or disfavors either Party will apply to the interpretation of this Agreement. Instead, this Agreement will be interpreted according to the fair meaning of its terms. The captions or headings of this Agreement are for convenience of reference only. They will not limit or otherwise affect the meaning or interpretation of any provision of this Agreement. The words "includes" and "including" are not limiting in any way and mean "includes without limitation" or "including without limitation." The word "person" includes individuals, corporations, partnerships, limited liability companies, co-operatives, associations and other natural and legal persons. The term "and/or" means each and all of the persons, words, provisions or items connected by that term; i.e., it has a joint and several meaning. The word "will" is a synonym for the word "shall". All attachments to this Agreement are a part of and are incorporated in this Agreement.

**15.10 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which will together be deemed to constitute one agreement. The Parties agree that the execution of this Agreement by exchanging pdf signatures, and/or by industry standard electronic signature software, shall have the same legal force and effect as the exchange of original signatures. In any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

**15.11 Force Majeure.** Except for in connection with QIAGEN's obligation to make payments to HTG under Section 4 above, no Party will be liable for, or will be considered to be in breach of or in default under this Agreement on account of, any delay or failure to perform any obligation under this Agreement to the extent such delay or failure is due to causes or conditions that are beyond such Party's reasonable control and that such Party is unable to overcome through the exercise of commercially-reasonable efforts. If any force majeure event occurs, the affected Party will give prompt written notice to the other Party and will use commercially-reasonable efforts to minimize the impact of the event.

**15.12 Entire Agreement.** With respect to the subject matter hereof, this Agreement, including any Statement(s) of Work and Exhibits, is the entire agreement between the Parties and supersedes all prior discussions, representations, warranties and agreements, both written and oral between the Parties.

**15.13 Integration**. This Agreement sets forth the entire understanding of the Parties with respect to the subject matter hereof, supersedes all existing agreements between them concerning such subject matter.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the date set forth herein by their duly authorized representatives.

| **HTG MOLECULAR DIAGNOSTICS, INC. "HTG"** | **QIAGEN MANCHESTER LIMITED** "**QIAGEN**" |
|---|---|
| By: /s/ Timothy B. Johnson | By: /s/ Douglas Liu |
| Timothy B. Johnson<br>President and Chief Executive Officer | Douglas Liu<br>Print Name<br>SVP Global Operations<br>Title |
| November 16, 2016<br>Date | November 16, 2016<br>Date |

**EXHIBIT A**

**Statement of Work Template**

THIS STATEMENT OF WORK (this "SOW") is made and entered into as of _____, 20___ (the "SOW Effective Date") by and between HTG Molecular Diagnostics, Inc. ("HTG") and QIAGEN Manchester Limited ("QIAGEN"). This SOW is made a part of, and shall be governed by, the terms and conditions of the Master Assay Development, Commercialization and Manufacturing Agreement (the "MSA") executed between the Parties dated as of November ___, 2016. In the event of a conflict between the terms and conditions of this SOW and those of the MSA, the MSA shall govern unless otherwise expressly provided herein.

1. Term
2. Description of Project
3. Definitions
4. Specific Details of Development Work
5. Milestones and Deadlines
6. Compensation Provisions (including Transfer Price calculation)
7. Clinical Supply Manufacturing Provisions
8. Intellectual Property and Licenses
9. Project Suspension and Termination

IN WITNESS WHEREOF, HTG and QIAGEN have executed this SOW by their respective officers hereunto duly authorized on the day and year written below.

| **HTG MOLECULAR DIAGNOSTICS** | | **QIAGEN Manchester Limited** | |
|---|---|---|---|
| By: | [template – not for signature] | By: | [template – not for signature] |
| Name: | _____ | Name: | _____ |
| Title: | _____ | Title: | _____ |
| Date: | _____ | Date: | _____ |

**Exhibit 10.24**

***Execution Copy***

# STOCK PURCHASE AGREEMENT

**This Stock Purchase Agreement** (this ***"Agreement"***) is made as of November 16, 2016 (the ***"Effective Date"***), by and between **HTG Molecular Diagnostics, Inc.**, a Delaware corporation (the ***"Company"***), and **QIAGEN North American Holdings, Inc.**, a California corporation (the ***"Purchaser"***).

**Whereas,** the Company wishes to sell to the Purchaser, and the Purchaser wishes to purchase from the Company, shares of the Company's common stock, par value $0.001 per share (***"Common Stock"***), on the terms and subject to the conditions set forth in this Agreement.

## Agreement

In consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Purchaser hereby agree as follows:

## 1. Definitions

Capitalized terms used and not otherwise defined herein shall have the respective meanings set forth below:

**1.1** ***"Action"*** has the meaning set forth in Section 3.12.

**1.2** ***"Affiliate"*** means, with respect to any Person, another Person that controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than 50% of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than 50% of the equity interest with the power to direct the management and policies of such non-corporate entities. For the purposes of this Agreement, in no event will the Purchaser or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor will the Company or any of its Affiliates be deemed Affiliates of the Purchaser or any of its Affiliates.

**1.3** ***"Board Approval"*** means, with respect to a specified matter or action, the approval of such matter or action by at least a majority of the members of the Company's Board of Directors at a duly authorized meeting of the Company's Board of Directors or pursuant to an action taken by unanimous written consent of the Company's Board of Directors.

**1.4** ***"Change of Control"*** will occur if: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of the Company, or if the percentage ownership of such person or entity in the voting securities of the Company is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition

or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of the Company; (b) a merger, consolidation, recapitalization, or reorganization of the Company is consummated, other than any such transaction which would result in stockholders or equity holders of the Company immediately prior to such transaction owning at least 50% of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of the Company approve a plan of complete liquidation of the Company, or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than any such sale or disposition to an Affiliate of the Company or to an entity of which more than 50% of the combined voting power of its voting securities are beneficially owned by stockholders of the Company in substantially the same proportions as their beneficial ownership of the outstanding voting securities of the Company immediately prior to such sale or disposition; or (d) individuals who, as of the date hereof, constitute the Board of Directors of the Company (the ***"Incumbent Board"***) cease for any reason to constitute at least a majority of the Board of Directors of the Company (*provided, however*, that any individual becoming a director subsequent to the date hereof whose election or appointment, or nomination for election by the Company's stockholders, was approved or recommended by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of the Company).

**1.5** ***"Closing"*** means the First Tranche Closing or the Second Tranche Closing, as applicable.

**1.6** ***"Closing Date"*** means the First Tranche Closing Date or the Second Tranche Closing Date, as applicable.

**1.7** ***"Common Stock Equivalents"*** means any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock (collectively, ***"Convertible Securities"***), or any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of, or voting or other rights of, shares of Common Stock.

**1.8** ***"Disposition"*** or ***"Dispose of"*** means any (i) pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

**1.9** ***"Evaluation Date"*** has the meaning set forth in Section 3.8.

**1.10** ***"Exchange Act"*** means the United States Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

**1.11** ***"FDA"*** has the meaning set forth in Section 3.17(a).

**1.12** ***"FDA Law and Regulations"*** has the meaning set forth in Section 3.17(a).

**1.13** ***"First Tranche Closing"*** means the closing of the sale and purchase of the First Tranche Shares.

**1.14** ***"First Tranche Closing Date"*** means the Effective Date or such other date or time as the Company and the Purchaser may mutually agree.

**1.15** ***"First Tranche Purchase Price"*** means the product of (x) the number of shares of Common Stock to be purchased under this Agreement at the First Tranche Closing, as determined in accordance with the definition of "First Tranche Shares" set forth below, multiplied by (y) the Share Price.

**1.16** ***"First Tranche Shares"*** means the number of shares of Common Stock to be purchased under this Agreement at the First Tranche Closing, which shall be equal to (i) $2,000,000 divided by (ii) the Share Price, rounded down to the nearest whole number; provided that in no event shall such number of shares exceed 19.9% of the issued and outstanding shares of Common Stock of the Company as of immediately after the First Tranche Closing.

**1.17** ***"Governmental Authority"*** means any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

**1.18** ***"HTG Qualified Financing"*** means the first financing consummated by the Company after the Effective Date in which the Company sells shares of Common Stock and/or shares of Preferred Stock for an aggregate purchase price of at least $12,000,000, before deduction of any underwriting or similar commissions, compensation or concessions paid or allowed by the Company in connection with such transaction and without deduction of any expenses payable by the Company, and including, for the avoidance of doubt, any such sale to an Affiliate of the Company that is done on an arm's length basis.

**1.19** ***"Intellectual Property Rights"*** has the meaning set forth in Section 3.14.

**1.20** "***Liens***" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

**1.21** ***"Lock-Up Term"*** has the meaning set forth in Section 8.2.

**1.22** ***"Material Adverse Effect"*** means a material adverse effect upon the business, assets, properties, operations, condition (financial or otherwise) or results of operations of the

Company and its Subsidiaries, taken as a whole, or in the Company's ability to perform its obligations under this Agreement.

**1.23** ***"Permitted Transferee"*** means (i) an Affiliate of the Purchaser that is wholly owned, directly or indirectly, by the Purchaser, or (ii) an Affiliate of the Purchaser that wholly owns, directly or indirectly, the Purchaser.

**1.24** ***"Person"*** means any individual, limited liability company, partnership, firm, corporation, association, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

**1.25** ***"Qualified Financing Purchase Price"*** means (i) with respect to any sale of shares of Common Stock in the HTG Qualified Financing, the price per share at which shares of Common Stock are sold, (ii) with respect to any sale of shares of Preferred Stock in the Qualified Financing, the price per share determined by dividing (a) the aggregate purchase price paid for such shares of Preferred Stock by (b) the aggregate number of shares of Common Stock issuable upon conversion of such shares of Preferred Stock (determined as of the closing of the HTG Qualified Financing without regard to any limitations on conversion that relate to Nasdaq Listing Rule 5635 or a holder's beneficial ownership of Common Stock), reduced to reflect the reasonable value of preferential rights of such shares of Preferred Stock over the Common Stock, and (iii) with respect to any sale of shares of both Common Stock and Preferred Stock in the HTG Qualified Financing, the weighted average of the Qualified Financing Purchase Price determined in accordance with the foregoing clauses (i) and (ii), respectively, based on aggregate purchase price for shares of Common Stock and Preferred Stock sold in such HTG Qualified Financing.

**1.26** ***"SEC"*** means the United States Securities and Exchange Commission.

**1.27** ***"SEC Filings"*** means all reports, forms, statements and other documents filed by the Company with the SEC since May 5, 2015 pursuant to the requirements of the Exchange Act, including material filed pursuant to Section 13(a) or 15(c) of the Exchange Act, in each case, together with all exhibits, supplements, amendments and schedules thereto, and all documents incorporated by reference therein.

**1.28** ***"Second Tranche Closing"*** means the closing of the sale and purchase of the Second Tranche Shares.

**1.29** ***"Second Tranche Closing Date"*** has the meaning set forth in Section 2.4.

**1.30** ***"Second Tranche Purchase Price"*** means the product of (i) the number of Second Tranche Shares, as determined in accordance with the definition set forth below, multiplied by (ii) the Qualified Financing Purchase Price.

**1.31** ***"Second Tranche Shares"*** means the number of shares of Common Stock to be purchased under this Agreement at the Second Tranche Closing, which shall be equal to (i) $2,000,000 divided by (ii) the Qualified Financing Purchase Price, rounded down to the nearest whole number; provided that in no event shall such number of shares, collectively with the

number of First Tranche Shares, exceed (A) if and only if the weighted-average price per share of Common Stock purchased at the First Tranche Closing and to be purchased at the Second Tranche Closing would be less than the greater of (x) the most recently reported consolidated closing bid price of the Common Stock (as reported on the Nasdaq Stock Market) prior to the execution of this Agreement and (y) the Company's most recently reported net tangible book value per share prior to the date of this Agreement (the ***"Nasdaq 20% Limitation"***), 19.9% of the issued and outstanding shares of Common Stock of the Company as of immediately prior to the execution of this Agreement and (B) 19.9% of the issued and outstanding shares of Common Stock of the Company as of immediately after the issuance of the Second Tranche Shares (the ***"Nasdaq Change of Control Limitation"*** and together with the Nasdaq 20% Limitation, the ***"Nasdaq Limitations"***). In the event either the Nasdaq 20% Limitation or Nasdaq Change of Control Limitation applies, the number of shares of Common Stock that shall constitute the Second Tranche Shares shall be appropriately reduced to the maximum number of shares of Common Stock that may be issued under this Agreement in the Second Tranche Closing without violating either of the Nasdaq Limitations.

**1.32** ***"Securities Act"*** means the United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

**1.33** ***"Shares"*** means the number of shares of Common Stock to be purchased under this Agreement, which shall include the First Tranche Shares and the Second Tranche Shares, as applicable.

**1.34** ***"Shares of Then Outstanding Common Stock"*** means, at the time of determination, the then issued and outstanding shares of Common Stock, as well as all capital stock that, as a result of any stock split, stock dividend or reclassification of Common Stock, is distributable (without any further action by the Company's Board of Directors or stockholders) on a pro rata basis to all holders of Common Stock.

**1.35** ***"Share Price"*** means $2.40.

**1.36** ***"Standstill Term"*** has the meaning set forth in Section 7.2.

**1.37** "***Subsidiary***" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

**1.38** ***"Third Party"*** means any Person (other than a Governmental Authority) other than the Purchaser, the Company or any of their respective Affiliates.

**2. Agreement to Sell and Purchase.**

**2.1 Authorization of Shares.** The Company has authorized the sale and issuance to the Purchaser of the Shares under the terms and conditions of this Agreement.

**2.2 Sale and Issuance of Common Stock.** On the basis of the representations and warranties herein, and upon the terms and subject to the conditions hereof, the Purchaser agrees to purchase from the Company, and the Company agrees to issue and sell to the Purchaser, (i) at

the First Tranche Closing, the First Tranche Shares at a price per share equal to the Share Price, and (ii) at the Second Tranche Closing, the Second Tranche Shares at a price per share equal to the Qualified Financing Purchase Price.

**2.3 First Tranche Closing.** Subject to the satisfaction or waiver of the conditions set forth herein, the First Tranche Closing shall take place on the First Tranche Closing Date at the offices of Cooley llp, 4401 Eastgate Mall, San Diego, California 92121 or at such other place as the Company and the Purchaser may agree in writing. At the First Tranche Closing, the Company shall instruct its transfer agent to credit the First Tranche Shares in book entry form for the benefit of, and in the name of, the Purchaser against the Purchaser's payment to the Company of the First Tranche Purchase Price by wire transfer of immediately available funds in accordance with wire instructions provided by the Company to the Purchaser prior to the First Tranche Closing.

**2.4 Second Tranche Closing.** Subject to the satisfaction or waiver of the conditions set forth herein, the Second Tranche Closing shall take place at the offices of Cooley llp, 4401 Eastgate Mall, San Diego, California 92121, or at such other place as the Company and the Purchaser may agree in writing, on the date on which the HTG Qualified Financing closes (the date on which the Second Tranche Closing actually occurs being referred to herein as the "***Second Tranche Closing Date***"), but in no event later than six months following the First Tranche Closing Date. At the Second Tranche Closing, the Company shall instruct its transfer agent to credit the Second Tranche Shares in book entry form for the benefit of, and in the name of, the Purchaser against the Purchaser's payment to the Company of the Second Tranche Purchase Price by wire transfer of immediately available funds in accordance with wire instructions provided by the Company to the Purchaser prior to the Second Tranche Closing.

**3. Representations, Warranties and Covenants of the Company**.

The Company hereby represents and warrants to the Purchaser as of each applicable Closing Date as follows:

**3.1 Organization, Good Standing and Qualification**. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business. The Company is duly qualified to transact business as a corporation and is in good standing in each jurisdiction in which the failure so to qualify would have a Material Adverse Effect upon the Company's ability to perform its obligations under this Agreement. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents.

**3.2 Authorization; Due Execution.** The Company has the requisite corporate power and authority to enter into this Agreement and to perform its obligations under the terms of this Agreement. All corporate action on the part of the Company, its officers, directors and, if applicable, stockholders, necessary for the authorization, execution and delivery of this Agreement has been taken. This Agreement has been duly authorized, executed and delivered by the Company and, upon due execution and delivery by the Purchaser, this Agreement will be a valid and binding obligation of the Company, enforceable against the Company in accordance

with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

**3.3 Subsidiaries**. All of the direct and indirect subsidiaries of the Company are set forth on Schedule 3.3. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries in this Agreement shall be disregarded.

**3.4 Capitalization**. Except as may be set forth in the SEC Filings, the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. Except as may be set forth in the SEC Filings, no Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except as may be set forth in the SEC Filings, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchaser) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all applicable federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. Assuming the accuracy of the Purchaser's representations and warranties set forth in Sections 4.3 and 4.4 hereof, no further approval or authorization of any stockholder, the board of directors of the Company or others is required for the issuance and sale of the Shares. Except as may be set forth in the SEC Filings, there are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

**3.5 Valid Issuance of Stock.** The Shares, when issued, sold and delivered in accordance with the terms of Section 2 hereof for the consideration and on the terms and conditions set forth herein, will be duly and validly authorized and issued, fully paid and nonassessable, free and clear of all Liens (other than any Liens that may be created by or imposed upon the Purchaser or its Affiliates), and, based in part upon the representations of the

Purchaser in this Agreement, will be issued in compliance with all applicable United States federal and state securities laws.

**3.6 No Defaults**. There exists no default under the provisions of any instrument or agreement evidencing, governing or otherwise relating to any material indebtedness of the Company, or with respect to any other agreement, a default under which would have a material adverse effect upon the Company's ability to perform its obligations under this Agreement.

**3.7 SEC Filings; Financial Statements.** The Company has timely filed with the SEC all SEC Filings. The SEC Filings were prepared in accordance with and, as of the date on which each such SEC Filing was filed with the SEC, complied in all material respects with the applicable requirements of the Exchange Act. None of such SEC Filings, at the time filed, contained an untrue statement of a material fact, or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Filings comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (***"GAAP"***), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal year-end audit adjustments (which are not expected to be material either individually or in the aggregate).

**3.8 Sarbanes-Oxley; Internal Accounting Controls**. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective and applicable to the Company as of the date hereof, and any and all applicable rules and regulations promulgated by the SEC thereunder that are effective as of the date hereof and as of the applicable Closing Date. The Company and its Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and its Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and its Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and its Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the ***"Evaluation Date"***). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers

about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

**3.9 Governmental Consents.** No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with any Governmental Authority on the part of the Company is required in connection with the consummation of the transactions contemplated by this Agreement, except for such notices required or permitted to be filed with certain United States state and federal securities commissions after the Effective Date, which notices (if required) will be filed on a timely basis.

**3.10 No Conflict.** The Company's execution, delivery and performance of this Agreement does not violate (i) any provision of the Company's Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws, each as amended as of the date hereof (copies of which have been filed with the SEC), (ii) any provision of any order, writ, judgment, injunction, decree, determination or award to which the Company is a party or by which it is bound, or (iii) to the Company's knowledge, any law, rule or regulation currently in effect having applicability to the Company.

**3.11 Material Changes; Undisclosed Events, Liabilities or Developments**. Since the date of the latest audited financial statements included within the SEC Filings, except as specifically disclosed in a subsequent SEC Filing filed prior to the date hereof: (i) there has been no event, occurrence or development that has had or that would reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the SEC, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans timely reported pursuant to Section 16 of the Exchange Act at least one (1) trading day prior to the date that this representation is made. Other than with respect to that certain Master Assay Development, Commercialization and Manufacturing Agreement, in negotiation between the parties or executed on or about the date hereof, by and between QIAGEN Manchester Limited and the Company (the ***"Development Agreement"***), the Company does not have pending before the SEC any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement and the entry into the Development Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) trading day prior to the date that this representation is made.

**3.12 Litigation**. Except as may be set forth in the SEC Filings, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an ***"Action"***) which (i) adversely affects or challenges the legality, validity or enforceability of any of the transactions contemplated by this Agreement or the Shares or (ii) would, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the SEC involving the Company or any current director or officer of the Company. The SEC has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

**3.13 Tax Status**. The Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

**3.14 Intellectual Property**. The Company and its Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as described in the SEC Filings as necessary or required for use in connection with their respective businesses (collectively, the ***"Intellectual Property Rights"***). Except as would not reasonably be expected to have a Material Adverse Effect, neither the Company nor any of its Subsidiaries has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within three (3) years from the date of this Agreement. Except as disclosed in the SEC Filings or with respect to a matter occurring after the date hereof which has been promptly disclosed in writing to the Purchaser prior to the Second Tranche Closing, neither the Company nor any of its Subsidiaries has received, since the date of the latest audited financial statements included within the SEC Filings, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, and to the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

**3.15 Compliance.** Except as may be set forth in the SEC Filings, neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as would not have or reasonably be expected to result in a Material Adverse Effect.

**3.16 Regulation M Compliance**. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company in violation of Regulation M of the Exchange Act.

**3.17 FDA; FDCA**.

**(a)** The Company and its Subsidiaries are conducting and have conducted their business and operations in material compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et. seq., and all applicable regulations promulgated by the United States Food and Drug Administration (***"FDA"***) (collectively, the ***"FDA Law and Regulations"***) and comparable foreign regulatory or governmental authorities.

**(b)** Except as set forth on Schedule 3.17(b) or as may be set forth in an applicable SEC Filing, neither the Company nor its Subsidiaries has received any notice or communication from the FDA alleging noncompliance with any applicable FDA Law and Regulation. The Company and its Subsidiaries are not subject to any enforcement, regulatory or administrative proceedings by the FDA or any comparable foreign regulatory or governmental authority and, to the knowledge of the Company, no such proceedings have been threatened. There is no civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, proceeding or request for information pending against Company or its Subsidiaries, and, to the knowledge of the Company, the Company and its Subsidiaries have no liability (whether actual or contingent) for failure to comply with any FDA Law and Regulation or any law or regulation of a comparable foreign regulatory or governmental authority. There is no act, omission, event, or circumstance of which the Company or its Subsidiaries have knowledge that would reasonably be expected to give rise to or lead to any such action, suit, demand, claim, complaint, hearing, investigation, notice, demand letter, warning letter, proceeding or request for information or any such liability. There has not been any violation of any FDA Law and Regulation or any law or regulation of a comparable foreign regulatory or governmental authority by the Company or its Subsidiaries in

their product development efforts, submissions, record keeping and reports to FDA or a comparable governmental authority that would reasonably be expected to require or lead to investigation, corrective action or enforcement, regulatory or administrative action that would result in a Material Adverse Effect. To the knowledge of Company, there are no civil or criminal proceedings relating to the Company or its Subsidiaries or any Company or Subsidiary employee which involve a matter within or related to the FDA's jurisdiction or the jurisdiction of any comparable governmental authority.

**3.18 Regulatory Permits**. Except as set forth in the SEC Filings, the Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Filings, except where the failure to possess such permits would not reasonably be expected to result in a Material Adverse Effect, and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any such permit.

**3.19 Foreign Corrupt Practices; Office of Foreign Assets Control.** Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or Affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

**3.20 Accountants**. The Company's independent registered accounting firm is identified in the SEC Filings. To the knowledge of the Company, such accounting firm: (i) is a registered public accounting firm as required by the Exchange Act and (ii) will express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2016.

**3.21 Insurance.** The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged. Neither the Company nor any Subsidiary has been notified that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

**3.22 Investment Company**. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as

amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

**3.23 Disclosure**. Except with respect to the material terms and conditions of the transactions contemplated by this Agreement and of the transactions contemplated by the Development Agreement, neither the Company nor any other Person acting on its behalf has provided the Purchaser or its agents or counsel with any information that it believes constitutes or might constitute material, non-public information. All of the disclosure furnished by or on behalf of the Company to the Purchaser regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that the Purchaser does not make or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 4 hereof.

**4. Representations, Warranties and Covenants of the Purchaser.**

The Purchaser hereby represents and warrants to the Company as of each Closing Date as follows:

**4.1 Organization and Good Standing**. The Purchaser is an entity duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or organization, and has all requisite corporate power and authority to carry on its business.

**4.2 Authorization; Due Execution.** The Purchaser has the requisite corporate power and authority to enter into this Agreement and to perform its obligations under the terms of this Agreement. All corporate action on the part of the Purchaser, its officers, directors and shareholders necessary for the authorization, execution and delivery of this Agreement have been taken. This Agreement has been duly authorized, executed and delivered by the Purchaser, and, upon due execution and delivery by the Company, this Agreement will be a valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

**4.3 No Current Ownership in the Company.** Other than the Shares acquired or to be acquired under this Agreement, the Purchaser does not own any shares of Common Stock or any Common Stock Equivalents as of immediately prior to the applicable Closing.

**4.4 Purchase Entirely for Own Account.** The Shares to be purchased by the Purchaser at the applicable Closing are being acquired for investment for the Purchaser's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same. The Purchaser does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participation to such person or to any third party, with respect to the Shares, if issued.

**4.5 Disclosure of Information.** The Purchaser has received all the information that it has requested and that it considers necessary or appropriate for deciding whether to enter into this Agreement and to acquire the Shares. The Purchaser further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Shares.

**4.6 Investment Experience.** The Purchaser acknowledges that it can bear the economic risk of its investment and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares. The Purchaser has not been organized solely for the purpose of acquiring the Shares.

**4.7 Accredited Investor.** The Purchaser is an "accredited investor" as such term is defined in Rule 501 of the General Rules and Regulations promulgated by the SEC pursuant to the Securities Act.

**4.8 Restricted Securities.** The Purchaser understands that:

**(a)** the Shares will not be registered under the Securities Act by reason of a specific exemption therefrom, and that the Purchaser must, therefore, bear the economic risk of such investment, unless and until a subsequent disposition thereof is registered under the Securities Act or is exempt from such registration, such as under Rule 144 of the Securities Act (***"Rule 144"***);

**(b)** the Shares, whether represented by a physical stock certificate or in book entry form, will be endorsed, stamped or otherwise notated with the following legends (in addition to any legend required by applicable state securities laws):

**(i)** THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "*ACT*") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED.

**(ii)** THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO, AND TRANSFERABLE ONLY IN ACCORDANCE WITH, THE TERMS AND CONDITIONS OF A CERTAIN STOCK PURCHASE AGREEMENT BY AND BETWEEN THE STOCKHOLDER AND THE COMPANY. COPIES OF SUCH AGREEMENT MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE COMPANY.

**(c)** The Company will instruct its transfer agent not to register the transfer of any Shares unless (1) the conditions specified in the legend contained in Section 4.8(b)(i) are satisfied and (2) (A) such Shares are transferred to a Person that is not bound or required to be bound by the restrictions contained in Sections 7 and 8 hereof or (B) the Standstill Term and the Lock-Up Term have expired or terminated, *provided* that any transfer described in the foregoing clause (A) or (B) also shall have been in compliance with all applicable provisions of this Agreement.

**4.9 No Short Sales.** The Purchaser has not engaged, and will not engage, in any short sales of the Common Stock within the three month period prior to the applicable Closing Date.

**4.10 No Legal, Tax or Investment Advice.** The Purchaser understands that nothing in the SEC Filings, this Agreement or any other materials presented to the Purchaser in connection with the purchase and sale of the Shares constitutes legal, tax or investment advice and that independent legal counsel has reviewed these documents and materials on the Purchaser's behalf. The Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

**5. Conditions to the Company's Obligations at Closing.**

The Company's obligation to sell, issue and deliver the Shares to the Purchaser at each Closing shall be subject to the following conditions, to the extent not waived by the Company:

**5.1 Representations and Warranties.** The representations and warranties made by the Purchaser in Section 4 hereof shall be true and correct in all material respects on the applicable Closing Date.

**5.2 Obligations.** The Purchaser shall have performed and complied with all obligations and conditions required to be performed and complied with by the Purchaser under this Agreement on or prior to the applicable Closing Date.

**6. Conditions to the Purchaser's Obligations At Closing.**

The Purchaser's obligation to tender payment of the First Tranche Purchase Price and the Second Tranche Purchase Price, as applicable, and accept delivery of the Shares at the applicable Closing shall be subject to the following conditions, to the extent not waived by the Purchaser:

**6.1 Representations and Warranties.** The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects on the applicable Closing Date.

**6.2 Obligations.** The Company shall have performed and complied with all obligations and conditions to be performed and complied with by the Company under this Agreement on or prior to the applicable Closing Date.

**7. Restrictions on Beneficial Ownership.**

**7.1 Standstill**. During the Standstill Term, neither the Purchaser nor any of its Affiliates (collectively, the ***"Standstill Parties"***) will (and the Purchaser shall cause its Affiliates not to), except to the extent expressly authorized in advance by Board Approval:

**(a)** directly or indirectly acquire beneficial ownership of any Shares of Then Outstanding Common Stock, and/or any Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Common Stock and/or Common

Stock Equivalents; provided, however, that an acquisition of shares of Common Stock pursuant to a stock split, a stock dividend or a recapitalization of the Company shall not be deemed to violate the provisions of this Section 7;

**(b)** directly or indirectly seek to have called any meeting of the stockholders of the Company, propose or nominate any person for election to the Company's Board of Directors or cause to be voted any Shares of Then Outstanding Common Stock in favor of any person for election to the Company's Board of Directors whose nomination has not been approved in advance by Board Approval;

**(c)** directly or indirectly, solicit proxies or consents, or become a "participant" in a "solicitation" (as such terms are defined in Regulation 14A under the Exchange Act), without prior Board Approval, or in opposition to the recommendation of the Company's Board of Directors, with respect to any matter, or seek to advise or influence any Person, in each case with respect to voting of any Shares of Then Outstanding Common Stock of the Company;

**(d)** deposit any Shares of Then Outstanding Common Stock in a voting trust or subject any Shares of Then Outstanding Common Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Common Stock (other than as expressly contemplated by this Agreement);

**(e)** propose (i) any merger, consolidation, business combination, tender or exchange offer, purchase of the Company's assets or businesses, or similar transaction involving the Company or (ii) any recapitalization, restructuring, liquidation or other extraordinary transaction with respect to the Company;

**(f)** act in concert with any Third Party to take any action in clauses (a) through (e) above, or form, join or in any way participate in a "partnership, limited partnership, syndicate, or other group" within the meaning of Section 13(d)(3) of the Exchange Act; or

**(g)** enter into discussions, negotiations, arrangements or agreements with any Third Party relating to the foregoing actions referred to in (a) through (f) above; provided, however, that nothing contained in this Section 7.1 prohibits the Purchaser or its Affiliates from acquiring a company or business that owns Shares of Then Outstanding Common Stock and/or Common Stock Equivalents provided that any such securities of the Company so acquired will be subject to the provisions of this Section 7.

**7.2 Standstill Term.** As used in this Agreement, the ***"Standstill Term"*** means the period commencing on the date of this Agreement and continuing until the occurrence of the earliest to occur of:

**(a)** the date that is six (6) months after the First Tranche Closing Date; provided, however, that if the Second Tranche Closing occurs during such six (6) month period, then the Standstill Term shall extend to the date that is nine (9) months after the Second Tranche Closing Date;

**(b)** provided that none of the Standstill Parties has materially violated Section 7.1, the date on which a Third Party publicly announces a tender, exchange or other offer for the Common Stock or proposal that, if consummated, would result in a Change of Control;

**(c)** the date that the Company publicly announces that it has entered into a letter of intent relating to a Change of Control, publicly announces its intent to do so or publicly announces that it is pursuing a transaction that would reasonably be expected to result in a Change of Control;

**(d)** the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

**(e)** a liquidation or dissolution of the Company.

**8. Restrictions on Dispositions.**

**8.1 Lock-Up**. During the Lock-Up Term, except to the extent expressly authorized by prior Board Approval, the Purchaser shall not, and shall cause its Affiliates not to, Dispose of (x) any of the Shares, together with any shares of Common Stock issued in respect thereof as a result of any stock split, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (x) of this sentence (collectively, the ***"Lock-Up Securities"***); provided, however, that the foregoing shall not prohibit the Purchaser from (A) transferring Lock-Up Securities to a Permitted Transferee, provided that any Lock-Up Securities so transferred remain subject to the provisions of this Section 8, or (B) Disposing of any Lock-Up Securities in order to reduce the beneficial ownership of the Standstill Parties to 19.9%, or such lesser percentage as advised in good faith and in writing by the Purchaser's certified public accountants that would be necessary pursuant to applicable accounting rules and guidelines so as to not require the Purchaser to include in its financial statements its portion of the Company's financial results, of the Shares of Then Outstanding Common Stock.

**8.2 Lock-Up Termination**. As used in this Agreement, the ***"Lock-Up Term"*** means, with respect to a Lock-Up Security, the period commencing on the date of this Agreement and continuing until the occurrence of the earliest to occur of:

**(a)** the date that is twelve (12) months after the applicable Closing Date at which such Lock-Up Security is purchased;

**(b)** immediately prior to the consummation of a Change of Control;

**(c)** a liquidation or dissolution of the Company; and

**(d)** the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

**8.3 Certain Tender Offers**. Notwithstanding any other provision of this Section 8, this Section 8 shall not prohibit or restrict any Disposition of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (a) a tender offer by a Third Party which is not opposed by the Company's Board of Directors (but only after the Company's filing of a Schedule 14D-9, or any amendment thereto, with the SEC disclosing the recommendation of the Company's Board of Directors with respect to such tender offer) or (b) an issuer tender offer by the Company.

**9. Miscellaneous.**

**9.1 Survival.** The representations and warranties contained herein shall survive each Closing and the delivery of the Shares thereat.

**9.2 Waivers and Amendments.** Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of both the Company and the Purchaser.

**9.3 Severability.** If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision(s) shall be excluded from this Agreement and the balance of this Agreement shall be interpreted as if such provision(s) were so excluded and shall be enforceable in accordance with its terms.

**9.4 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to conflicts of law principles that would result in the application of the laws of another jurisdiction.

**9.5 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Facsimile and electronic (PDF) signatures shall be as effective as original signatures.

**9.6 Successors and Assigns.** Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party. Subject to the preceding sentence, the rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

**9.7 Entire Agreement.** This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and neither party will be liable or bound to the other party in any manner by any oral or written warranties, representations, or covenants except as specifically set forth herein.

**9.8 Payment of Fees and Expenses.** Each of the Company and the Purchaser shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable

attorneys' fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled. The Company shall pay all transfer agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company), stamp taxes and other taxes and duties levied in connection with the delivery of any Shares to the Purchaser.

**9.9 Broker's Fee.** Each of the Company and the Purchaser hereby represents that there are no brokers or finders entitled to compensation in connection with the sale of the Shares, and each party shall indemnify the other party for any such fees for which such party is responsible.

**9.10 Notices.** All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (i) upon personal delivery to the party to be notified; (ii) upon transmission when sent by confirmed facsimile if sent during normal business hours of the recipient, and if sent at a time other than the normal business hours of the recipient, then on the day on which normal business hours of the recipient next commence; (iii) seven calendar days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) two business days after deposit with an internationally recognized overnight courier with written verification of receipt. All communications shall be sent to the other party hereto at the mailing address or facsimile number set forth below, or at such other mailing address or facsimile number as such party may designate by 10 days' advance written notice to the other party hereto.

**(a)** If to the Company, notices shall be addressed to:

HTG Molecular Diagnostics, Inc.
3430 E. Global Loop
Tucson, AZ 85706
Attn: Chief Executive Officer
Facsimile: (520) 547-2837

*With a copy to:*

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Steven M. Przesmicki, Esq.
Facsimile: (858) 550-6420

**(b)** If to the Purchaser, notices shall be addressed to:

QIAGEN NORTH AMERICAN HOLDINGS, INC.
19300 Germantown Road
Germantown, MD 20874
Attention: General Counsel

With copies to:
Dr. Philipp von Hugo
QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany
Facsimile: 011 49 2103 29 21844

*With a copy to:*

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: Daniel Follansbee
Facsimile: 617-542-2241

**9.11 Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

**9.12 Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY NATURE, EXPRESS OR IMPLIED, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT.

**9.13 Limitation of Liability**. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

**9.14 WAIVER OF JURY TRIAL.** IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

**[Signature Page Follows]**

**In Witness Whereof**, the parties hereto have caused this Stock Purchase Agreement to be executed by their duly authorized representatives as of the day and year first above written.

**HTG Molecular Diagnostics, Inc.**

By: /s/ Timothy B. Johnson
Timothy B. Johnson
*President and Chief Executive Officer*

**QIAGEN North American Holdings, Inc.**

By: /s/ Roland Sackers
Roland Sackers
*Chief Financial Officer QIAGEN*

**Exhibit 23.1**

Consent of Independent Registered Public Accounting Firm

HTG Molecular Diagnostics, Inc.
Tucson, Arizona

We hereby consent to the incorporation by reference in the Registration Statements on Form S8 (Nos. 333-210401, 333-208325 and 333-203930) of HTG Molecular Diagnostics, Inc. of our report dated March 23, 2017, relating to the financial statements which appear in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Phoenix, Arizona

March 23, 2017

**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 annual report on Form 10-K for the year ended December 31, 2016 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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 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: March 23, 2017

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 annual report on Form 10-K for the year ended December 31, 2016 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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 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: March 23, 2017

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 Annual Report of HTG Molecular Diagnostics, Inc. (the "Company") on Form 10-K for the period ending December 31, 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, 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 result of operations of the Company.

Date: March 23, 2017

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 Annual Report of HTG Molecular Diagnostics, Inc. (the "Company") on Form 10-K for the period ending December 31, 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, 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 result of operations of the Company.

Date: March 23, 2017

By: /s/ Shaun D. McMeans

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