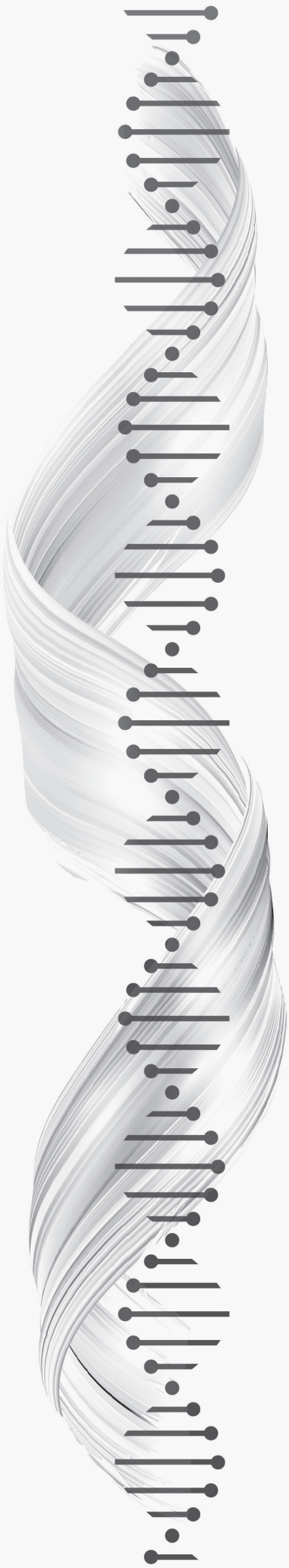


HTG

HTG Molecular Diagnostics, Inc. Annual Report 2018

Dear Stockholders,

I want to personally thank you for your continued support in our mission to develop next-generation diagnostics that advance precision medicine. 2018 has been another great year for HTG, as we consistently execute on our business strategy and continue to make significant strides toward our future goals. We take great pride in seeing our technology help researchers and Pharma partners better understand the mechanisms of disease and seeing customers use that knowledge to develop therapies that can improve the lives of patients.

As we look back on the past year, we see our HTG EdgeSeq™ technology being selected and used by researchers for its unique capabilities, such as its small, less invasive sample requirements and its highly multiplexed capabilities, both of which fit squarely into today's health economic realities. We believe the broader macro trends in precision medicine, including more information from smaller samples at a more economical cost, support and will continue to drive our business. Specifically, we view the following trends to be very advantageous to our business strategy:

- Increasing investments in biomarker-based research and development by large biopharmaceutical companies to develop therapies with deep durable response and fewer side effects.

- Continued efforts to obtain more clinical information from smaller samples and less invasive biopsies.

- Accelerating adoption of next-generation sequencing (NGS) by clinical laboratories driving the need for simplified workflows and cost-effective solutions falling within the current reimbursement environment.

We are also pleased with the progress we made in the last year. Some of our 2018 key accomplishments include:

- Grew our total revenues by 46% in 2018 compared to the prior year, reflecting our consistent execution and continued success in growing our profiling business with Pharma company customers.

- Entered into a Master Agreement with Oncologie, Inc., an innovative biotechnology company with operations in Boston and China, for biomarker development in immuno-oncology.

- Expanded a Statement of Work (SOW) with one of our Pharma partners to enable the use of investigational use only (IUO) assays in additional disease indications. The SOW is contracted through our Master Assay Development, Commercialization and Manufacturing Agreement with QIAGEN Manchester Limited.

- Introduced a new HTG EdgeSeq Precision Immuno-Oncology Panel featuring 1,392 genes to enable researchers to explore immuno-oncology applications, such as immuno-phenotyping, tumor inflammation status and the study of immune resistance pathways.

- Introduced a new HTG EdgeSeq Mouse mRNA Tumor Response Panel featuring 1,600 genes for use in mouse oncology models to identify and quantify expression of genes and gene pathways. This panel moves HTG technology further upstream in the Pharma process and enables customers to use the HTG technology platform from discovery to the clinic.

- Established HTG Molecular Diagnostics France SARL, a new subsidiary based in France, expanding our commercial scope and broadening our customer support resources in Europe.

- Opened an applications laboratory in Sausheim, France to provide expanded customer support, biomarker related services and sample processing to our growing customer base in Europe.

- Expanded our agreement with Illumina to allow for potentially new in vitro diagnostic (IVD) test development in auto-immune, cardiovascular and fibrosis disorders and diseases, adding to our current agreement in oncology. We believe Pharma's increasing interest in biomarker-based diagnostics will eventually lead to a companion diagnostic leveraging our HTG EdgeSeq technology and Illumina's sequencing technology.

- Opened a development facility in San Carlos, California where we plan to develop new proprietary IVD diagnostic assays starting with a breast cancer diagnostic assay. We also expect to develop diagnostics in lung cancer and lymphoma in the future. We envision this 5,000 square foot facility becoming HTG's Molecular Diagnostic (MDx) Center of Excellence, attracting key technical talent in the Bay Area, accelerating our MDx product development and complementing our Tucson facility, which is focused on RUO and Pharma product development.

- Introduced HTG EdgeSeq Reveal software, a powerful software product that streamlines the analysis of biomarker data and enables applications such as immunophenotyping of tumor infiltrating lymphocytes, monitoring of immunotherapy response biomarkers and elucidating immune escape mechanisms known to drive disease progression.

2019 and Our Vision for the Future

As we look forward, we are excited by the number of near-term and long-term opportunities. We believe our EdgeSeq technology and HTG business model offer clear advantages that set us apart from others in the industry – such as our low sample requirements, our high multiplex capability, our ability to simplify NGS workflows, our strong Pharma partnerships and pipeline and our strong development teams. Our customers are just beginning to unlock the potential of our technology. Things to expect from us and our business in the coming months include:

- Continued growth in our RUO profiling products and services business. This business reflects increasing customer adoption helping to fuel our existing business, setting the stage for growth in our Pharma pipeline.

- Continued growth in our Pharma clinical trial pipeline, measured quarterly by the number of programs and the number of unique customers. We anticipate adding one or two new IUO programs per year.

- Building our diagnostic product development business, as we begin development and move toward commercialization of HTG proprietary diagnostics first in breast cancer, then lung cancer and finally, lymphoma.

In closing, I want to thank our employees, customers and all of our collaborators for their tireless efforts and support this past year. As a Company, we continue to see significant year over year progress in building both our business and our organizational capabilities, allowing us to deliver on our mission of improving the lives of patients through the power of precision medicine. I am excited and energized by the opportunities ahead for HTG and look forward to our continued success.

We appreciate your support and look forward to another successful year.

John Lubniewski

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, 2018

OR

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

FOR THE TRANSITION PERIOD FROM_____TO

Commission File Number 001-37369

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 Capital 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit 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, a smaller reporting company or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if he registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

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 Capital Market on June 29, 2018, was $90,728,255.

The number of shares of Registrant's Common Stock outstanding as of March 1, 2019 was 28,606,012.

Table of Contents

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 Consolidated 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," "continue," "seek," "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 revenue from our products and services and drive revenue streams, including molecular diagnostic ("MDx") revenue;
- our ability to secure regulatory clearance or approval, domestically and internationally, for the clinical use of our products;
- our ability to develop new technologies to expand our product offerings, including direct-target sequencing for detection of mutations in genomic DNA and/or expressed RNA (such as single-point mutations and gene rearrangements, including gene fusions and insertions), and methods to detect mutation load and microsatellite instability;
- the activities anticipated to be performed by us and third parties under design and development projects and programs, and the expected benefits and outcomes of such projects and programs;
- the implementation of our business model and strategic plans for our business;
- the regulatory landscape for our products, domestically and internationally;
- our strategic relationships, including with holders of intellectual property relevant to our technologies, manufacturers of next-generation sequencing ("NGS") instruments and consumables, critical component suppliers, distributors of our products, and third parties who conduct our clinical studies;
- our intellectual property position;
- our ability to comply with the restrictions of our debt facility and meet our debt obligations;
- our expectations regarding the market size and growth potential for our life sciences and diagnostic businesses;
- our expectations regarding trends in the demand for sample processing by our biopharmaceutical company customers;
- any estimates regarding expenses, future revenue and capital requirements; 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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. 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 life sciences company focused on advancing the promise of precision medicine. Our product and service solutions are based on our proprietary next generation digital HTG EdgeSeq technology that enables the detection and measurement of biomarkers using a small amount of biological sample, in liquid or solid forms. Our menu of HTG EdgeSeq assays are automated on our HTG EdgeSeq platform, which applies genetic sequencing tools that generate expression data in a timely manner utilizing a simplified workflow for customers. We seek to leverage key business drivers in molecular profiling for biomarker analysis and diagnostics, including the acceleration of precision medicine, the migration of molecular testing to NGS-based applications, the movement to smaller and less invasive biopsies, the need for greater diagnostic sensitivity, the need to conform to challenging healthcare economics and the need for automation and an easily deployable workflow. For example, these capabilities enable customers to extend the use of limited biological samples for retrospective analysis, gaining further understanding of the molecular drivers of disease with the goal of developing biomarker-driven targeted therapies. We also believe our technology can be used in clinical applications that will simplify, consolidate and reduce the cost of NGS-based diagnostic workflows and in commercialized companion diagnostic ("CDx") tests.

In 2014, we launched our HTG EdgeSeq technology, which generates a molecular profiling library for detection of RNA using NGS. Our HTG EdgeSeq assays are automated on our HTG EdgeSeq platform. Our innovative platform and menu of molecular profiling panels are being utilized in two complimentary ways in advancing precision health. Biopharmaceutical companies and other translational research centers utilize our technology to discover and validate biomarkers which can identify patient populations most likely to respond to certain therapies. The capability to analyze hundreds or thousands of genes from a small biological sample allows customers to more economically unlock substantial amounts of molecular data. In addition to purchasing our technology for use in customer facilities, customers can also obtain the advantages of our proprietary technology through our service offerings. Pre-clinical services, including custom assay development and sample processing services provided by our VERI/O laboratory, allow customers the ability to more efficiently identify and validate biomarker signatures across their drug portfolios. Our ISO 13485 2018 quality system and diagnostic development teams also partner with biopharmaceutical company customers to develop, manufacture and commercialize companion diagnostics. Although our initial focus is oncology, we offer customers a full solution from biomarker discovery to deployment of CDx tests across all disease states. Clinical testing labs face significant challenges in adopting NGS-based workflows and the HTG EdgeSeq platform was designed to address many of these challenges such as high sample loads, RNA extraction and other costly and complex workflow processes. Utilizing NGS as our method of detection provides our customers with the benefits of our highly multiplexed and extraction-free chemistry and the sensitivity and dynamic range of the sequencers, providing a powerful value proposition and complete workflow.

Our HTG EdgeSeq platform is currently focused on RNA-based applications, which we believe is an area of significant unmet need and where we have demonstrated competitive advantages. In addition to expanding our applications in RNA, we are developing our HTG EdgeSeq technology to analyze DNA in biological samples, as we expect the market to express a growing need for multi-modal testing and analysis.

Our products include instrumentation (or platforms), consumables, including assay kits, and software analytics that, as an integrated system, automate sample workflow and can quickly, robustly and simultaneously profile tens, hundreds or thousands of molecular targets from samples a fraction of the size required by many prevailing technologies. Our objective is to establish our solutions as the standard in biomarker development and molecular diagnostics, and to make their benefits accessible to all molecular labs from research to the clinic. We believe that our target customers desire high quality molecular profiling information in a multiplexed panel format from increasingly smaller and less invasive samples, with the ability to test and analyze such information locally to minimize turnaround time and cost.

We believe customer utilization of our HTG EdgeSeq technology will drive the following three distinct but synergistic revenue streams:

1. Research use only ("RUO") profiling revenue associated with biomarker programs in biopharmaceutical companies and other translational research centers. Customers access our technology by purchasing our HTG EdgeSeq platform and/or utilizing our VERI/O service lab capabilities. The number of early stage biomarker programs utilizing our technology has been growing steadily and we expect this number to continue to grow as we launch new profiling panels. We expect some of these programs to advance to late-stage programs that will require diagnostic grade investigational use only ("IUO") assays for use in clinical trials, which is a driver of our second revenue stream, collaboration service revenue.

2. Collaborative development services revenue associated with companion diagnostic development programs for biopharmaceutical companies. Our HTG EdgeSeq technology is utilized to develop, seek regulatory approval for and commercialize CDx assays for biopharmaceutical drug candidates and corresponding therapeutics. In November 2016, we entered into a Master Assay Development, Commercialization and Manufacturing Agreement (the "Governing Agreement") with QIAGEN Manchester Limited ("QML"), a wholly owned subsidiary of QIAGEN N.V. in the field of oncology. We have also entered into collaborative development agreements directly with biopharmaceutical company customers in other fields. Alone, or in partnership with QML, we have entered into four companion diagnostic agreements

to date, of which two are actively generating collaborative development services revenue as of December 31, 2018. Collaborative development services revenue has been and is expected to continue to fluctuate significantly from period to period as this revenue is heavily milestone-driven such that delays in completion or acceptance of project milestones and biopharmaceutical company customer internal timeline adjustments result in periods of varying levels of development activity that is often difficult to forecast. We believe this is an important component of our business due to the possibility of successful late stage programs leading to commercialization of CDx tests in multiple geographies. We believe such commercialization would contribute significantly to our third expected revenue stream.

3. Our third developing revenue stream, MDx revenue, which represents the sale of our regulated diagnostic products, is expected to begin initial ramp in 2019. We plan to generate MDx revenue from three primary sources:

    - companion diagnostic assays resulting from our biopharmaceutical collaborations;
    - diagnostic partnerships resulting from our collaborations with European key opinion leaders; and
    - proprietary diagnostic assays developed by us.

As of December 31, 2018, we sell two internally developed proprietary CE/IVD marked assays, including our HTG EdgeSeq DLBCL Cell of Origin Assay EU and HTG EdgeSeq ALKPlus Assay EU. Several additional diagnostic tests are in early stage development, which we expect to drive this category of revenue in future periods.

To facilitate further our ability to generate European MDx revenue and improve our responsiveness to customer needs on a local level, we formed of a French subsidiary, HTG Molecular Diagnostics France SARL ("HTG France"), in November 2018. We plan to have HTG France operate an applications incubator laboratory in Sausheim, France, providing application support and biomarker program services for our European collaborations. We expect HTG France to provide similar biomarker program services to those provided by our VERI/O laboratory in the United States, on a much smaller scale, in the second half of 2019.

In the first quarter of 2019, we announced the initiation of a program for the clinical development of a comprehensive breast cancer molecular diagnostic assay. This program will be headquartered in a new development facility in the San Francisco Bay Area of California. Our Chief Scientific Officer, Dr. Maureen Cronin, will oversee this new breast cancer program and Dr. Joseph Sparano of the Albert Einstein College of Medicine has agreed to lead our scientific advisory board for the program. Dr. Cronin and Dr. Sparano have extensive experience in breast cancer and breast cancer diagnostics which we expect to provide significant benefit throughout this development process. In addition, Laura Beggrow, our President, Diagnostics, will lead our diagnostic initiatives, including the daily management of the breast cancer program's development team and collaboration with our key opinion leaders.

Our Strategy

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. The key components of our strategy are:

- *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, 2018, we had 75 active early stage development programs across leading biopharmaceutical companies which are incorporating biomarkers and potentially companion diagnostics in their drug development programs. 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 RNA and DNA profiling tests that can provide important biomarker information in emerging areas of immuno-oncology, auto-immune and other disease areas.
- *Develop new proprietary molecular diagnostic panels with high medical utility*. Our HTG EdgeSeq platform was developed with features that we believe solve many of the issues facing NGS-based workflows. Our technology 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 formalin-fixed paraffin-embedded ("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.

- *Establish our systems workflow as the best solution for clinical sequencing*. We intend to continue to establish our technology as the best complimentary workflow 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, Inc., Thermo Fisher Scientific, Inc. and QML, to position our HTG EdgeSeq products as the benchmark for workflow in targeted sequencing applications.
- *Expand the addressable market of our technology through new applications and expansion into new liquid biopsies*. We have demonstrated technical feasibility for several new applications that are intended to allow us to measure DNA mutations directly and/or in expressed RNA and improve the already-high sensitivity of our HTG EdgeSeq assays. These and other planned 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. As biopsies continue to utilize less invasive methods, it will be important to expand our applicability to new liquid samples such as PAXgene, platelets and exosomes.

Our Market Opportunities

Cancer Molecular Profiling and Genomics in Life Science Research

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. The HTG EdgeSeq technology coupled with NGS is 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.

The market for molecular profiling in cancer is expected to be $8.9 billion by 2022. The genomics market, to which our technology is broadly applicable, is expected to reach over $22.0 billion in the same timeframe.

Therapy Driven Diagnostics - Companion Diagnostics

The World Health Organization estimates that cancer will lead to the death of 11.5 million people by 2030. While progress has been made, it is commonly accepted that cancer therapies are not helping enough patients. As a result, biopharmaceutical companies are aggressively deploying biomarker driven strategies to improve the response rates to existing and new drugs in development. These companies are looking for technology solutions that can more effectively identify the biological root causes of disease and aid the discovery on biomarkers to better develop and target drugs to the right patients. The companion diagnostic market is currently estimated at $2.6 billion and growing approximately 20% annually. We believe that the acceleration of investment into immunotherapy drugs will also be a catalyst for future companion diagnostics for combination therapies where RNA gene expression classification is expected to be important.

When a molecular biomarker panel is used for selection of patients in a Phase 2 or 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 U.S. Food and Drug Administration ("FDA") approval or clearance of the CDx test, the patient must be tested with the CDx test prior to being treated 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.

Molecular Diagnostics – NGS-based Workflows

Complexities and Challenges of Molecular Diagnostics 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 ("IHC"), fluorescent *in situ* hybridization ("FISH"), polymerase chain reaction ("PCR"), gene expression arrays ("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 many 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, smaller sample sizes, sample logistics and information flow has created significant challenges for labs, physicians and patients.

Our Solution

At the core of our solution is our proprietary chemistry known as quantitative nuclease protection ("qNPA"). Our qNPA-based chemistries provide a sensitive and efficient method for analyzing DNA and RNA as it eliminates the need for DNA or RNA extraction and other complex processes. We designed and developed our 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.

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

- *Optimize sample utilization*. Our 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 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-quantitative PCR ("qRT-PCR"), our chemistry does not require 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 36 hours. Additionally, our HTG EdgeSeq system 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 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.

Our Competitive Advantages

We believe that our HTG EdgeSeq technology provides us with a number of competitive advantages that set us apart from others in our industry and that will continue to drive new customers toward our solutions. Such advantages include:

- Proprietary and patent-protected HTG EdgeSeq technology enabling researchers and clinical labs the ability to capture information encompassing up to thousands of genes from extremely small sample sizes with the sensitivity and dynamic range of next generation sequencers;
- Industry partnerships with leading NGS companies enabling the development and commercialization of next generation molecular diagnostics utilizing the combined power of HTG EdgeSeq and NGS technology;
- Partnerships with leading biopharmaceutical companies and a fast-growing pipeline of early and late stage biomarker programs expected to generate significant opportunities for companion diagnostic products;
- Strengthening market position solidified by comprehensive product and service capabilities ranging from custom assay development, retrospective sample analysis, in vitro diagnostic ("IVD") assay development, regulatory submission support, global companion diagnostic commercialization capabilities available as a result of key contractual relationships and a robust automation platform for democratization of NGS-based molecular profiling; and
- A highly experienced senior management team.

Current Commercial Panels Offered on the HTG EdgeSeq Platform

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:

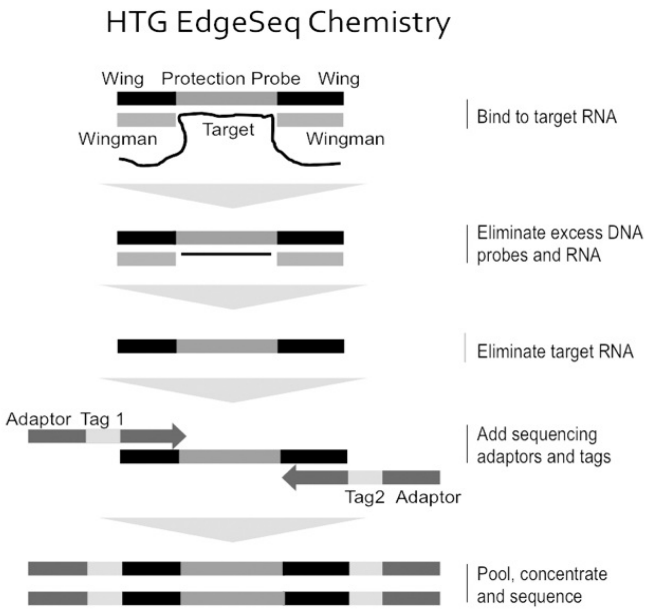
- *HTG EdgeSeq Oncology Biomarker Panel*. This RNA expression panel measures the expression of up to 2,560 genes implicated in cancer for profiling tumor tissues, analyzing cancer pathways and identifying new biomarkers across both solid tumors and hematolymphoid neoplasms. We worked with key opinion 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 miRNA Whole-Transcriptome Assay (below), we provide customers with a comprehensive solution for profiling their large sample archives for novel expression signatures.
- *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 ("ABC") or germinal center B-cell like ("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 PATH Assay.* The HTG EdgeSeq PATH Assay has been designed for retrospective gene expression profiling ("GEP") to compliment traditional immunohistochemistry ("IHC") testing by allowing investigators to assess mRNA expression of 470 targets when tissue availability is limited. The assay enables a wide variety of applications, including pre-screening of samples to guide subsequent testing and development of novel gene signatures.
- *HTG EdgeSeq miRNA 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 miRNA 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 EdgeSeq DLBCL Cell of Origin Assay EU*. The HTG EdgeSeq DLBCL Cell of Origin Assay EU is an IVD assay that uses GEP to determine the cell of origin ("COO") subtype of DLBCL tumors from FFPE tissue section. The gene expression data are assessed by a classification algorithm and the tumor samples are determined to be of the ABC, GCB or unclassified subtype. This product has obtained CE-marking in Europe where it is available for diagnostic use. It is not for sale in North America.
- *HTG EdgeSeq ALKPlus Assay EU.* The HTG EdgeSeq ALK*Plus* Assay EU is an IVD NGS-based assay sold in the EU intended to measure and analyze mRNA ALK gene fusion events in FFPE lung tumor specimens from patients previously diagnosed with non-small cell lung cancer ("NSCLC"). This product has also obtained CE-marking in Europe where it is available for diagnostic use. It is not for sale in North America.
- *HTG EdgeSeq EGFR, KRAS and BRAF Mutation Assay (VERI/O lab service offering exclusively).* The HTG EdgeSeq EGFR, KRAS, and BRAF Mutation Assay is an RUO assay currently available exclusively as a VERI/O laboratory service and detects 23 mutations in EGFR, KRAS and BRAF from a 5 µm section of FFPE tissue. Retrospective analysis of the tumor's mutational status may help researchers understand the tumor response to targeted therapy. This assay is extraction-free and can be used with small samples such as a needle core biopsy.
- *HTG EdgeSeq Precision Immuno-Oncology Panel*. The NGS-based HTG EdgeSeq Precision Immuno-Oncology Panel is designed to measure the immune response both inside the tumor and the surrounding microenvironment. By leveraging the high sensitivity and dynamic range of NGS instrumentation, this powerful tool measures 1,392 genes from a single section of FFPE tissue, extracted RNA or PAXgene samples.

Our Technology

HTG EdgeSeq Chemistry

Our HTG EdgeSeq chemistry is shown schematically in the figure below. 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.



Key Advantages of our HTG EdgeSeq Chemistry

- *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) and improves utilization of precious samples, thereby 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, we believe 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 qRT-PCR, 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 Instrument Platform

Our assays and instruments were developed internally and are manufactured in Tucson, AZ under ISO 13485:2006 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 EdgeSeq platform, 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 EdgeSeq platform (shown above) consists 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 six processors allowing laboratories to easily expand their capacity by adding processors.

Applications of our HTG EdgeSeq technology combine the HTG EdgeSeq processor with a 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 a 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.

In addition to direct sales of our systems, we utilize several alternative arrangements to sell our systems. Our platform 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, 2018, we had an installed base of 49 instruments (consisting of 32 systems sold, three covered under reagent rental agreements, seven evaluation units and seven systems with key opinion leaders) and an additional three instruments installed at third-party sites in support of companion diagnostic collaboration projects.

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 completed the CE marking of the HTG EdgeSeq ALK*Plus* Assay EU in Europe in March 2017 as a companion diagnostic for ALK positive therapies in NSCLC lung cancer cases. Information on the ROS1, RET, NTRK1 and HER2 gene rearrangements included in the ALK*Plus* Assay panel is 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 for certain late-stage drug development trials, and, as appropriate, receive FDA approval in the future. Our PMA application for the HTG EdgeSeq Alk*Plus* Assay in the U.S. market, which we initiated in 2016, is currently on hold as we evaluate additional medical content for this assay. We also CE/IVD marked our HTG EdgeSeq DLBCL COO EU test in October 2015, which is utilized to differentiate the two main sub-types of DLBCL, ABC and GCB. We expect these two CE/IVD marked assays to begin generating revenue in 2019.

We have also initiated early development on a comprehensive assay intended to allow for breast cancer prognosis and prediction. Over the past decade, significant molecular information and understanding of breast cancer biology has emerged, which we believe has created a substantial opportunity to develop a broader and more comprehensive set of markers and signatures to support clinical decision making using a single panel. We estimate that this type of panel could serve a target market of nearly 400,000 patients in Europe and North America, alone; an available market of $200.0 million with the assumption of an average selling price per test of $500.

We are leveraging our platform to develop comprehensive molecular profiling panels across an increasing set of molecular applications, with initial focus in immuno-oncology and the identification of pathologies through molecular profiling ("next generation pathology"). In conjunction with our biopharmaceutical collaborators, we plan to develop novel RNA-based gene panels and possibly classifiers that can provide information about inflammation signatures and the molecular classification of tumors. Separately, we also plan to develop novel RNA-based gene panels designed for expanded applications in immune health monitoring and prescreening, detection of hyper-progression and predicting patient response to combination therapies. We believe that 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. We expect this to require substantial effort from our research scientists and the use of various laboratory equipment, supplies and materials, which together represent the most significant costs that we expect to incur in connection with the development of these applications and profiling panels.

Serving the decentralized markets with Project JANUS

In 2016, we began the development of our next generation instrument, referred to as Project JANUS, with the intent to potentially increase our addressable market for instrument sales to include the thousands of laboratories that make up the lower throughput clinical market. 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 would be well suited for managing low, medium, and surge testing volumes, thereby assisting our customers with this unpredictable aspect of their businesses. We expect testing panels for Project JANUS to include mutations, fusions, expression classifiers and a molecular surrogate for IHC. Upon development of this instrument, our approach would be to serve centralized markets with the HTG EdgeSeq system and expand service to the decentralized market of lower sample throughput laboratories with Project JANUS. Due to various research and development priorities, Project JANUS development efforts were put on hold during the third quarter of 2016. We intend to resume development efforts in accordance with development prioritization and availability of resources.

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, 2018, our research and development team consisted of 40 employees across the disciplines of research and development scientist, platform development and bioinformatics.

Our development team is responsible for clinical assay development services being performed for biopharmaceutical company customers, including those entered into in accordance with our Governing Agreement with QML. We believe these programs have the potential to generate future revenue through the sale of HTG EdgeSeq instruments and test kit annuities associated with a successfully approved companion diagnostic test as the related drug gains adoption. Our research efforts are currently focused on the expansion of our technology into new immune-oncology applications as well as other applications in solid and liquid biopsies, while working to continuously improve assay performance and probe design.

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, 2018, our U.S. sales and marketing organization consisted of 19 employees including eight in direct sales or sales management, four in sales support and seven in marketing. In addition to our U.S. sales team, as of December 31, 2018, we had eight 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, with distributors in Spain, Portugal, Italy and Israel.

Our sales and marketing efforts target 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 the 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 to influence utilization of our products.

Manufacturing and Suppliers

We primarily manufacture our products within our facility in Tucson, AZ. External resources are leveraged for their specific expertise in either producing components for our HTG EdgeSeq instrument 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 EdgeSeq instruments and reagent kits at our Tucson, Arizona facility, which has been certified to ISO 13485:2006 standards. We believe that our existing manufacturing capacity is sufficient to meet our needs for at least the next several years.

Instruments

We assemble our 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 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, Fluidigm Corporation, Illumina, Inc., Abbott Molecular, Luminex Corporation, Affymetrix, Inc., NanoString Technologies, Inc., entities owned and controlled by QIAGEN N.V., Roche Diagnostics, a division of the Roche Group of companies, Personal Genome Diagnostics and Thermo Fisher Scientific, Inc.;
- Centralized Clinical Laboratory Improvement Amendments ("CLIA") certified labs offering molecular profiling and gene expression tests as laboratory-developed tests ("LDTs") such as Foundation Medicine, Inc., Trovagene, Inc., Guardant Health, Inc. and Genomic Health, Inc.; and
- 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 report.

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 EdgeSeq platform 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, 2018, our patent portfolio included 14 patent families that, collectively, consisted of six issued U.S. patents, 35 granted foreign patents (variously in Australia, Canada, China, Japan, France, Germany, Italy, Spain, and United Kingdom), and 24 patent applications pending in the United States and foreign jurisdictions. This portfolio is directed to our nuclease-protection-based technologies, other nucleic-acid detection methods, and to methods for DLBCL and distinguishing indeterminate nevi from melanoma. Our patent portfolio will help us maintain an exclusive position in key areas of our business, including targeted nuclease-protection based sequencing, and DLBCL cell-of-origin applications of our technology. In addition, this portfolio may provide out-licensing opportunities, such as, for methods of detecting melanoma or detection of single-nucleotide changes. There were 10 granted patents, including one U.S. patent, directed to our novel HTG EdgeSeq methods in the portfolio as of December 31, 2018. The HTG EdgeSeq method patents will expire in April 2032. Our portfolio also included 14 applications as of December 31, 2018, seven for our direct-target sequencing (V2) HTG EdgeSeq methods and seven for our DLBCL subtyping methods, as well as a provisional application pending directed to detecting DNA and RNA in the same sample.

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."

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 Research, LLC ("NuvoGen") to acquire certain intellectual property from NuvoGen. The acquired technology generally relates to our former 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, thereafter, agreed to pay NuvoGen the greater of $400,000 per year or 6% of our annual revenue, until the total aggregate cash compensation paid to NuvoGen under the agreement equals $15,000,000. Pursuant to the latest amendment to the agreement, we paid NuvoGen an annual fixed fee of $800,000, in quarterly installments, for the year ended December 31, 2017. In addition, a revenue-based payment of $85,574 was made in the first quarter 2018, for the amount by which 6% of revenue exceeded the applicable fixed fee for the year ended December 31, 2017. Although the amendment allowed for the deferral of any accrued revenue-based payments through December 31, 2017, no revenue-based payments were deferred. Beginning in 2018, on an annual basis we are obligated to pay the greater of $400,000 or 6% of our annual revenue, until the total aggregate cash compensation paid to NuvoGen under the agreement totals $15,000,000. Revenue-based payments of $526,548 were made to NuvoGen during 2018 and an additional $363,686 was payable as of December 31, 2018, for the amount by which 6% of revenue exceeded the applicable fixed fee for revenue generated during the year ended December 31, 2018. As of January 1, 2018, and continuing until the remaining obligation has been paid in full, interest on the remaining unpaid obligation will accrue and compound annually at a rate of 2.5% per year. Accrued interest on this unpaid obligation is payable on the date that the remaining obligation is paid in full.

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.

MidCap Credit Facility

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

The MidCap Term Loan provides a secured term loan facility in an aggregate principal amount of up to $20.0 million. We borrowed the first advance of $7.0 million ("MidCap Tranche 1") on the closing date. Under the terms of the MidCap Term Loan, the second advance of $13.0 million ("MidCap Tranche 2") will be available on or before September 30, 2019, subject to our satisfaction of certain conditions described in the MidCap Term Loan.

MidCap Tranche 1 was used to repay in full all outstanding amounts and fees due under the Loan and Security Agreement we entered into in August 2014 with Oxford Finance LLC and Silicon Valley Bank (the "Growth Term Loan"). The proceeds remaining from MidCap Tranche 1 and, if borrowed, the proceeds from MidCap Tranche 2, are expected to be used for working capital and general corporate purposes.

MidCap Tranche 1, and if borrowed, MidCap Tranche 2, each bear interest at a floating rate equal to 7.25% per annum, plus the greater of (i) 1.25% or (ii) the one-month London interbank offered rate ("LIBOR"). Principal on each term loan advance is payable in 36 equal monthly installments beginning April 1, 2020 until paid in full on March 1, 2023. Prepayments of the term loans under the MidCap Term Loan, in whole or in part, will be subject to early termination fees in an amount equal to 3.0% of principal prepaid if prepayment occurs on or prior to the first anniversary of the MidCap Closing Date, 2.0% of principal prepaid if prepayment occurs after the first anniversary of the MidCap Closing Date but on or prior to the second anniversary of the MidCap Closing Date, and 1.0% of principal prepaid if prepayment occurs after the second anniversary of the MidCap Closing Date and prior to or on the third anniversary of the MidCap Closing Date. In connection with execution of the MidCap Term Loan, the Company paid MidCap a $100,000 origination fee. Upon termination of the MidCap Term Loan, the Company is required to pay an exit fee equal to 4.50% of the principal amount of all term loans advanced to us under the MidCap Term Loan.

The MidCap Term Loan also required that we deliver subordination documents with respect to the QNAH Convertible Note, or that the QNAH Convertible Note otherwise be converted or prepaid, on or before June 30, 2018, and required us to deposit approximately $3.3 million into an escrow account by July 15, 2018 if neither event occurred by such date. As neither event occurred prior to June 30, 2018, we deposited approximately $3.3 million into an escrow account on July 11, 2018. Such escrowed funds will be released to the Company upon subsequent delivery of the requisite subordination documents or conversion of the QNAH Convertible Note. If neither delivery of the subordination documents or conversion of the QNAH Convertible Note occurs, such funds will be applied by the escrow agent to repay in full the QNAH Convertible Note at maturity (or in connection with a prepayment at the direction of the Company), subject to certain conditions described in the MidCap Term Loan.

The MidCap Revolving Loan provides a secured revolving credit facility in an aggregate principal amount of up to $2.0 million. We may request an increase in the total commitments under the MidCap Revolving Loan by up to an additional $8.0 million, subject to agent and lender approval and the satisfaction of certain conditions. Availability of the revolving credit facility under the MidCap Revolving Loan will be based upon a borrowing base formula and periodic borrowing base certifications valuing certain of our accounts receivable and inventory, as reduced by certain reserves, if any. The proceeds of any loans under the MidCap Revolving Loan may be used for working capital and general corporate purposes.

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

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

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

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

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

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

LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market and is widely used as a reference for setting the interest rate on loans globally, is currently scheduled to be phased out in 2021. Before LIBOR is phased out, we may need to renegotiate the MidCap Credit Facility to replace LIBOR with a new standard, which has yet to be established. The consequences of these developments cannot be entirely predicted, but could result in higher interest rates on our loans under the MedCap Credit Facility.

Development and Component Supply Agreement with Illumina, Inc.

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

Under the Restated Agreement, the parties have agreed to continue activities under the first development plan which was entered into pursuant to the Original Agreement relating to our HTG EdgeSeq ALK*Plus* Assay. In addition, we may, at our discretion, submit additional development plans for IVD test kits in the Field to Illumina for its approval, not to be unreasonably withheld.

Under each development plan, Illumina will provide specified regulatory support and rights, and develop and deliver to us an executable version of custom software, which, when deployed on Illumina's MiSeqDx sequencer, would enable sequencing by the end-user of the subject IVD test kit probe library. Illumina retains ownership of the custom software, subject to our right to use the custom software in connection with the commercialization of IVD test kits. We are required to pay fees to Illumina upon achievement of specified regulatory milestones relating to the IVD test kits, though none of these regulatory milestones have been reached through December 31, 2018. We have also agreed to pay Illumina a single digit percentage royalty on net sales of any IVD test kits that we commercialize pursuant to the Restated Agreement.

Absent earlier termination, the Restated Agreement will expire in May 2027; however, Illumina is no longer obligated to notify us of changes in its products that may affect our IVD test kits after May 31, 2023. We may terminate the Restated Agreement at any time upon 90 days' written notice and may terminate any development plan under the Restated Agreement upon 30 days' prior written notice. Illumina may terminate the Restated Agreement upon 30 days' prior written notice if we undergo certain changes of control, subject to a transition period of up to 12 months for then-ongoing development plans. Either party may terminate the Restated Agreement upon the other party's material breach of the Restated Agreement that remains uncured for 30 days, or upon the other party's bankruptcy.

QIAGEN Agreements

Governing Agreement

In November 2016, we entered the Governing Agreement with QML. 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 jointly seek companion diagnostic programs with biopharmaceutical companies, QML enters into sponsor project agreements with interested biopharmaceutical companies for specified projects, and we and QML enter into statements of work, that set 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.

We and QML share net profits under each statement of work, at a percentage that primarily depends on which company's intellectual property forms the basis for the particular assay under the applicable statement of work. Each statement of work provides additional financial terms for the corresponding project, which terms depend on the respective development and/or commercialization activities of the parties.

The Governing Agreement has a five-year term, though either party may terminate the Governing 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, except neither party will have such change of control termination right to the extent the Governing Agreement relates to one of the statements of work entered into under the agreement. 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.

We have entered into three statements of work under the Governing Agreement to date, of which two remained active as of December 31, 2018. For additional information relating to the statements of work associated with our Governing Agreement see Item 8, "Notes to Consolidated Financial Statements."

Stock Purchase Agreement

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 our common stock on November 17, 2016 at $2.40 per share, for a total purchase price of $2.0 million. The purchase price for the shares of common stock purchased by QNAH on November 17, 2016 reflected the parties' agreement as to the fair market value of the shares as of the closing. However, the portion of the purchase price per share that exceeded the most recently reported closing price of our common stock, or $175,000 in the aggregate, was attributed to the Governing Agreement and recorded as deferred revenue to be recognized on a straight-line basis over the Governing Agreement's five-year term. No additional shares of our common stock were purchased by QNAH in the second tranche closing allowed for in this agreement and QNAH had no further obligation to purchase our common stock under the agreement.

QNAH Convertible Note Agreement

In October 2017, we issued a subordinated convertible promissory note (the "QNAH Convertible Note") to QNAH in the principal amount of $3.0 million against receipt of cash proceeds equal to such principal amount. The QNAH Convertible Note bears simple interest at the rate of 3.0% per annum and matures on October 26, 2020. QNAH may elect to convert all or any portion of the outstanding principal balance of the QNAH Convertible Note and all unpaid accrued interest thereon at any time prior to the maturity date into shares of our common stock at a conversion price of $3.984 per share.

Third-Party Coverage and Reimbursement

Clinical laboratories acquire our instrumentation through a capital purchase, capital lease or reagent purchasing agreement. These laboratories 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 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, molecular testing laboratories have multiple options for reimbursement coding, but we expect that the primary codes used will be the Genomic Sequencing Procedure codes. We are also monitoring the Protecting Access to Medicare Act implementation as well as the recent National Coverage Determination for NGS testing by the Centers for Medicare & Medicaid Services ("CMS").

Genomic Sequencing Procedures.

The AMA created codes for Genomic Sequencing Procedures ("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 ABC or GCB subtypes of diffuse large B-cell lymphomas;
- Gene rearrangements in solid tumors and hematolymphoid neoplasms; and
- 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 ("MACs") such as Novitas and Cahaba, and coverage for specific test codes are specified in Local Coverage Determinations ("LCDs") issued by individual MACs or National Coverage Determinations ("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 ("CAP") and the Association for Molecular Pathology ("AMP") and industry consultants; these trends are key considerations in our product development plans.

Our customers may use our products, if approved, and 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 22, 2017, gapfill pricing for CPTs 81445 and 81450 for the assessment of 5-50 genes in solid and liquid tumors, respectively, were set at $598 and $760, respectively, and remains the same as of December 31, 2018. CPT 81455 for the assessment of 51 or more genes in solid and liquid tumors was set at $2,920.

In 2018, CMS released its NCD for reimbursement of CDx tests in oncology. We believe this was a very important event as many of the diagnostic assays that we are in the process of developing are expected to be oncology CDx tests which would be addressed in this NCD.

We believe that establishment of the aforementioned reimbursement codes specific to genomic sequencing procedures such as our CDx tests currently in development is an important factor in expanding access to our products. In addition, coverage and reimbursement of our 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 coverage and sufficient 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.

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.

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 in the United States 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 companion diagnostic tests under development by HTG are classified as "medical devices" under the United States Food, Drug and Cosmetic Act ("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 ("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 ("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 ("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

An 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 ("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 currently effective directives is the In Vitro Diagnostic Medical Device Directive ("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 of the IVDD 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.

On May 26, 2017, the EU released a new regulatory framework, the In Vitro Diagnostic Medical Device Regulation ("IVDR") which is expected to replace IVDD. Our products in the EU will have to comply with the IVDR requirements after May 26, 2022. Until that time, our products must continue to meet the requirements of IVDD for commercialization in the EU.

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 EU, 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, significant criminal, civil and administrative penalties, damages, fines, disgorgement, 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 regulatory 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 regulatory 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 Federal 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 significant 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 ("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 ("HITECH") and their implementing regulations established uniform standards for 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 EU has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC ("Data Protection Directive"). The Data Protection Directive was replaced in May 2018 with the recently adopted European General Data Protection Regulation ("GDPR"), which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. Over time we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation, including the GDPR, in the EU countries in which we operate.

The Federal Physician Payments Sunshine Act

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 significant civil monetary penalties.

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.

California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018, the 2018 Appropriations Resolution, that extended the moratorium on the medical device excise tax through December 31, 2019. Absent further legislative action, the tax will be automatically reinstated for medical device sales beginning January 1, 2020.

Since its enactment in 2010, there have been judicial and Congressional challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the ACA and otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the "Tax Act") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2018 Appropriations Resolution delays the implementation of certain ACA-mandated fees, including, without limitation, the medical device excise tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace ACA will impact 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 the passage of other legislative amendments, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, 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 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.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("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

Our ability to retain current talent and recruit new employees into our Company is a critical factor in our continued growth and performance improvement. We continue to initiate programs to promote our organizational culture and to identify the best possible new talent as the organization grows and new positions are made available. As of December 31, 2018, we had 107 full-time and two part-time employees, of which 14 are employed in administration, 23 in manufacturing and operations, 40 in research and development, five in regulatory and quality affairs, and 27 in sales and marketing. Seven of these employees were located in Europe and all others were located 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. We and our French employees have agreed to the terms of the applicable collective bargaining agreements.

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 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) December 31, 2020, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion, or (b) 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 (3) 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.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934 (the "Exchange Act") and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

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 $16.5 million and $19.0 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $151.0 million. We expect that our losses will continue for the foreseeable future as we will be required to invest significant additional funds to support product development, including development of our next generation instrument platforms, development of our new HTG EdgeSeq panels, including our initial U.S. IVD assay, development of assays pursuant to our Governing Agreement with QML, and the commercialization of our HTG EdgeSeq system and proprietary consumables. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products and services. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products and services, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Numerous other factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, QML and two other customers accounted for 58%, 10% and 9% of our revenue, respectively, for the year ended December 31, 2018, and three customers accounted for 44%, 27% and 11% of our accounts receivable balance as of December 31, 2018. If orders from our top customers or the number of collaboration projects with QML are reduced or discontinued, our revenue in future periods may materially decrease. Fluctuations in our operating results may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Factors that may contribute to fluctuations in our operating results include many of the risks described under the caption “Risk Factors – Risks Related to Our Business and Strategy” of this report. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. Our products involve a significant capital commitment from our customers or may depend on customer studies that have variable or indefinite timelines and accordingly, involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. Also, activities performed under our Governing Agreement involve significant resource commitments by us and depend on QML activities over which we have limited control and on biopharmaceutical customer activities and studies that have variable or indefinite timelines and outcomes. We may expend significant effort in attempting to meet our development obligations under the Governing Agreement, the respective payments for which may occur in a different period. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on our past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

entering into additional service and custom RUO assay design agreements with biopharmaceutical customers will drive increased demand for our relatively high margin panels. If we are not able to successfully increase our installed base and biopharmaceutical customer relationships, then sales of our products and services, and our margins for these revenue items may not meet expectations. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products, including diagnostic products or services, would adversely affect our ability to improve our operating results.

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We 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.

For the years ended December 31, 2018 and 2017, approximately 69% and 71% of our revenue was generated from sales originated by customers located outside of the United States, respectively. We expect that a percentage of our future revenue will continue to come from international sources, driven in part by activities conducted pursuant to our Governing Agreement, and we expect to expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export and import restrictions;
- various reimbursement, pricing and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers, including transfer pricing, value added and other tax systems, double taxation and restrictions and/or taxation on repatriation of earnings;
- tariffs, customs charges, bureaucratic requirements and other trade barriers;

- difficulties and costs of staffing and managing foreign operations, including difficulties and costs associated with foreign employment laws;
- increased financial accounting and reporting burdens and complexities; and
- difficulties protecting, procuring, or enforcing intellectual property rights, including from reduced or varied protection for intellectual property rights in some countries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We currently rely on a single supplier to supply a subcomponent used in our HTG EdgeSeq processors. While we periodically forecast our needs for this subcomponent, our contract with this supplier, which may be a standard purchase order, does not commit them to carry inventory or make available any particular quantities, and the supplier may give other customers' needs higher priority than ours and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If we were to lose this supplier, we may not be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, or at all. If we should encounter delays or difficulties in securing the quality and quantity of subcomponent we require for our processors, our supply chain would be interrupted which would adversely affect our sales. A loss of this supplier could significantly delay the delivery of our HTG EdgeSeq processor, which in turn would materially affect our ability to generate revenue. If any of these events occur, our business and operating results could be materially harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pursuant to the terms of an asset purchase agreement with NuvoGen, we agreed to annually pay NuvoGen the greater of $400,000 or 6% of our yearly revenue until the total aggregate cash compensation paid to NuvoGen under the agreement equals $15.0 million. To date, we have paid NuvoGen approximately $8.0 million. Payments to NuvoGen will result in a reduction in our working capital as we continue to make payments on this obligation

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

Under the MidCap Credit Facility, our interest rate on borrowed amounts is dependent on the London interbank offered rate ("LIBOR"). LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market and is widely used as a reference for setting the interest rate on loans globally, is currently scheduled to be phased out in 2021. Before LIBOR is phased out, we may need to renegotiate the MidCap Credit Facility to replace LIBOR with a new standard, which has yet to be established. The consequences of these developments cannot be entirely predicted, but could result in higher interest rates on our loans under the MedCap Credit Facility. We cannot provide assurance that future interest rate changes will not have a material negative impact on our business, financial position, or operating results.

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

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness or modify existing debt agreements;
- amend or modify certain material agreements;
- engage in additional lines of business;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- change certain key management personnel or organizational documents; and
- engage in transactions with our affiliates.

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

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

As of December 31, 2018, we had federal net operating loss carryforwards ("NOLs") to offset future taxable income of approximately $138.8 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 (the "IRC"), a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period) is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We believe we may have already experienced one or more ownership changes and may in the future experience one or more additional ownership changes, and thus, our ability to utilize pre-ownership change NOLs and other pre-ownership change tax attributes to offset post-ownership change income may be limited. Such limitations may cause a portion of our NOL and credit carryforwards to expire. In addition, future changes in our stock ownership, including as a result of future financings, as well as changes that may be outside of our control, could result in ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

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

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

- disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

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

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

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

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

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

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

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

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

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

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

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

Changes in funding for the FDA, the Securities and Exchange Commission ("SEC") and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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, internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.

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

Risks Related to Government Regulation and Diagnostic Product Reimbursement

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.

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

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

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

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

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

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

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

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

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

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

The American Medical Association Current Procedural Terminology ("CPT") Editorial Panel created new CPT codes that could be used by our customers to report testing for certain large-scale multianalyte GSPs, including our diagnostic products, if approved. Effective January 1, 2015, these codes allow for uniform reporting of broad genomic testing panels using technology similar to ours. While these codes standardize reporting for these tests, coverage and payment rates for GSPs remain uncertain and we cannot guarantee that coverage and reimbursement for these tests will be provided in the amounts we expect, or at all. Initially, industry associations recommended that payment rates for GSPs be cross-walked to existing codes on the clinical laboratory fee schedule. On October 27, 2014, CMS issued preliminary determinations for 29 new molecular pathology codes, including the GSPs, of gapfill rather than crosswalking as recommended by the Association for Molecular Pathology. This means that local private MACs, such as Palmetto, Novidian, Novitas and Cahaba, were instructed to determine the appropriate fee schedule amounts in the first year, and CMS calculated a national payment rate based on the median of those local fee schedule amounts in the second year. This process may make it more difficult for our customers to obtain coverage and adequate reimbursement for testing services using our diagnostic products. We cannot assure that CMS and other third-party payors will establish reimbursement rates sufficient to cover the costs incurred by our customers in using our clinical diagnostic products, if approved. On September 22, 2017, gapfill pricing was set for three CPT codes which our customers may potentially utilize to obtain reimbursement, subject to regulatory limitations, for the use of our products. CPTs 81445 and 81450, for the assessment of 5-50 genes in solid and liquid tumors, respectively, were set at $598 and $760, respectively, and remains the same as of December 31, 2018. Additionally, CPT 81455 for the assessment of 51 or more genes in solid and liquid tumors was set at $2,920.

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

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

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

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

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

- The Federal Anti-kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation, rather, if one purpose of the remuneration is to induce referrals, the Federal Anti-Kickback Statute is violated.
- The federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral. Unlike the Federal Anti-Kickback Statute, the Stark Law is a strict liability statute, meaning that all of the requirements of a Stark Law exception must be met in order to be compliant with the law.
- Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other governmental third-party payors that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money to the Federal Government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the Federal Government, which may apply to entities that provide coding and billing advice to customers; the Federal Government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- HIPAA, which created additional federal civil and 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 covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, maintenance, or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. In addition, the EU has established its own data security and privacy legal framework, including but not limited to the recently adopted General Data Protection Regulation (EU) 2016/679 (“GDPR”), which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. Over time we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation, including the GDPR, in the EU countries in which we operate.
- California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act (“CCPA”), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to evolving regulatory environment related to personal data and protected 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.
- State law equivalents of each of the above federal laws, such as anti-kickback, self-referral, and false claims laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the Federal Government that otherwise restricts payments that may be made to healthcare providers; state laws that require device manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

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

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

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to, among other things: (i) comply with the regulations of the FDA, CMS, the Department of Health and Human Services Office of Inspector General ("OIG") and other similar foreign regulatory bodies; (ii) provide true, complete and accurate information to the FDA and other similar regulatory bodies; (iii) comply with manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with collaborators and key opinion leaders, as well as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such

actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

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

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

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

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

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. Further, the ACA includes a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, which became effective January 1, 2013. However, the Consolidated Appropriations Act of 2016, signed into law in December 2015, includes a two-year moratorium on the medical device excise tax through December 31, 2017. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 (the "2018 Appropriations Resolution") that extended the moratorium on the medical device excise tax through December 31, 2019. Absent further legislative action, the tax will be automatically reinstated for medical device sales beginning January 1, 2020. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. However, the future of the ACA is uncertain. There have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA. For example, the Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace ACA will impact ACA and our business. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

- We might not have been the first to make the inventions covered by each of our patents and pending patent applications.
- We might not have been the first to file patent applications for these inventions.
- Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies.
- It is possible that none of our pending patent applications will result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties.
- We may not develop additional proprietary products and technologies that are patentable.
- The patents of others may have an adverse effect on our business.
- We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

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

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

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

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

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

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

We might not be able to obtain licenses to technology or other intellectual property rights that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or multiple licenses may be needed for the same product (e.g., stacked royalties). We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our 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 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 consolidated financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Stock Market ("Nasdaq"). The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"). We have performed system and process evaluation and testing of our internal controls over financial reporting to allow management to report annually on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. This has required and will require that we incur substantial professional fees and internal costs to augment 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 consolidated financial statements, and our ability to accurately report our financial results could be adversely affected. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

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

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

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

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

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

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

We are an "emerging growth company," and a "smaller reporting company" and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies or smaller reporting 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 a "smaller reporting company", as defined in the Exchange Act, and for as long as we continue to be an "emerging growth company" or a "smaller reporting company", we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies" or "smaller reporting 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 (for so long as we are an "emerging growth company"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements (for so long as we are an "emerging growth company" or a "smaller reporting company"), 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 (for so long as we are an "emerging growth company"). We could be an "emerging growth company" for up to five years following the completion of our initial public offering in May 2015, however, we would cease to be an "emerging growth company" before the end of that five-year period as of the following December 31, if we have more than approximately $1.07 billion in annual revenue, or if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of the second fiscal quarter 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 will be a "smaller reporting company" until the market value of our common stock that is held by non-affiliates exceeds $250.0 million as of the last business day of our most recently completed second fiscal quarter. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Our Common Stock

We expect that our stock price will fluctuate significantly.

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

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new products, significant contracts, commercial relationships or capital commitments;
- failure to obtain or delays in obtaining product approvals or clearances from the FDA or foreign regulators;
- adverse regulatory or coverage and 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.

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

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

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

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.

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.

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties.

Our corporate facilities are comprised of 30,100 square feet of administrative, laboratory and manufacturing spaces 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 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.

In January 2019, we further amended the first lease to add approximately 7,000 square feet of additional administrative, manufacturing and laboratory space, effective July 1, 2019 or, if later, the actual date of occupancy, and continuing through expiration of the lease in January 2021. In connection with this lease amendment, the landlord has agreed to fund certain leasehold improvements, which will result in the capitalization of additional leasehold improvements when completed in the second half of 2019, which will be amortized over the shorter of the useful life of the leasehold improvements or the remaining lease term. Base rent for the additional leased space will be approximately $6,800 per month, commencing on the date of occupancy and extending through the remaining term of the lease.

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 Capital Market under the symbol "HTGM." Trading of our common stock on The Nasdaq Stock Market commenced on May 6, 2015 in connection with our initial public offering.

On March 1, 2019, the last reported sale price of our common stock was $2.77 per share.

Holders

As of March 1, 2019, there were approximately 173 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.

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 consolidated 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." All forward-looking statements included in this Annual Report are based on information available to us as of the time we file this Annual Report and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain.

Overview

We are a commercial stage life sciences company focused on advancing the promise of precision medicine. Our product and service solutions are based on our proprietary next generation digital HTG EdgeSeq technology that enables the detection and measurement of biomarkers using a small amount of biological sample, in liquid or solid forms. Our menu of HTG EdgeSeq assays are automated on our HTG EdgeSeq platform, which applies genetic sequencing tools that generate expression data in a timely manner utilizing a simplified workflow for customers. We seek to leverage key business drivers in molecular profiling for biomarker analysis and diagnostics, including the acceleration of precision medicine, the migration of molecular testing to NGS-based applications, the movement to smaller and less invasive biopsies, the need for greater diagnostic sensitivity, the need to confirm to challenging healthcare economics and the need for automation and an easily deployable workflow. For example, these capabilities enable customers to extend the use of limited biological samples for retrospective analysis, gaining further understanding of the molecular drivers of disease with the goal of developing biomarker-driven targeted therapies. We also believe our technology can be used in clinical applications that will simplify, consolidate and reduce the cost of NGS-based diagnostic workflows and in commercialized CDx tests.

Our products include instrumentation (or platforms), consumables, including assay kits, and software analytics that, as an integrated system, automate sample processing and can quickly, robustly and simultaneously profile tens, hundreds or thousands of molecular targets from samples a fraction of the size required by many prevailing technologies. Our objective is to establish our solutions as the standard in biomarker development and molecular diagnostics, and to make their benefits accessible to all molecular labs from research to the clinic. We believe that our target customers desire high quality molecular profiling information in a multiplexed panel format from increasingly smaller and less invasive samples, with the ability to test and analyze such information locally to minimize turnaround time and cost.

In 2014, we launched our HTG EdgeSeq technology, which generates a molecular profiling library for detection of RNA using NGS. Our HTG EdgeSeq assays are automated on our HTG EdgeSeq platform. Our innovative platform and menu of molecular profiling panels are being utilized in two complimentary ways in advancing precision health. Biopharmaceutical companies and other translational research centers utilize our technology to discover and validate biomarkers which can identify patient populations most likely to respond to certain therapies. In addition to purchasing our technology for use in customer facilities, customers can also obtain the advantages of our proprietary technology through our service offerings. Pre-clinical services, including custom assay development and sample processing services provided by our VERI/O laboratory, allow customers the ability to more efficiently identify and validate biomarker signatures across their drug portfolios. Our ISO 13485 2018 quality system and diagnostic development teams also partner with biopharmaceutical company customers to develop, manufacture and commercialize companion diagnostics. Although our initial focus is oncology, we offer customers a full solution from biomarker discovery to deployment of CDx tests across all disease states. Utilizing NGS as our method of detection provides our customers with the benefits of our highly multiplexed and extraction-free chemistry and the sensitivity and dynamic range of the sequencers, providing a powerful value proposition and complete workflow.

We have two primary sources of revenue: revenue from RUO profiling for biopharmaceutical companies, academic research centers and molecular testing laboratories; and revenue from collaborative development services for companion diagnostic development programs for biopharmaceutical companies. RUO profiling revenue includes customer purchases of our HTG EdgeSeq instrument and related RUO assay kits, and the use of our HTG EdgeSeq instrument and RUO assay kits to process samples on the customer's behalf in our VERI/O laboratory. Collaborative development revenue relates to services performed primarily for biopharmaceutical companies pursuant to our Governing Agreement with QML. Under the Governing Agreement, our HTG EdgeSeq proprietary technology is utilized to develop, seek regulatory approval for and commercialize companion diagnostic assays for biopharmaceutical drug candidates and corresponding therapeutics. This currently drives a laboratory services and collaborative development services-oriented revenue model. However, as discussed further below, we anticipate that this will be a catalyst toward an emerging product-based strategy in the long term as an increase in our menu of diagnostic panels is expected to result in increased demand for our instrument and consumables products in individual laboratories and customer locations.

A developing third category of revenue is MDx revenue, which represents the sale of our regulated diagnostic products. Our first products are in early stage commercialization in Europe but not yet providing meaningful revenue. To facilitate our ability to generate MDx revenue in Europe and to improve our responsiveness to customer needs on a local level, we formed HTG France in November 2018. HTG France will operate an applications laboratory in Sausheim, France, providing application support and customer service for our European accounts. We expect HTG France to provide similar sample processing services to those provided by our VERI/O laboratory in the United States, on a much smaller scale, in the second half of 2019.

We have incurred significant losses since our inception, and we have never been profitable. We incurred net losses of $16.5 million and $19.0 million for the years ended December 31, 2018 and 2017, respectively, and had an accumulated deficit of $151.0 million as of December 31, 2018. As of December 31, 2018, we had available cash and cash equivalents totaling approximately $8.4 million, investments in short-term corporate and government debt securities totaling $22.7 and had current liabilities of approximately $7.0 million and long-term liabilities of approximately $15.7 million, primarily attributable to our MidCap Term Loan, QNAH Convertible Note and NuvoGen obligations. We believe that our existing resources will be sufficient to fund our planned operations for at least the next 12 months from the issuance of these consolidated financial statements included elsewhere in this report. 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.

Recent Developments

In January 2019, we announced the initiation of a program for the clinical development of a comprehensive breast cancer molecular diagnostic assay. This program will be headquartered in a new development facility in the San Francisco Bay Area of California. Our Chief Scientific Officer, Dr. Maureen Cronin, will oversee this new breast cancer program and Dr. Joseph Sparano of the Albert Einstein College of Medicine has agreed to lead our scientific advisory board for the program. Dr. Cronin and Dr. Sparano have extensive experience in breast cancer and breast cancer diagnostics which we expect to provide significant benefit throughout this development process.

In February 2019, we entered into a fourth amendment of SOW Two under our Governing Agreement with QML. This amendment contemplates the use of the IUO assay developed in the previous phases of SOW Two in multiple biopharmaceutical company partner clinical trials and additional development activities which potentially could be included in a future companion diagnostic assay submission.

In March 2019, we appointed Laura Beggrow, a seasoned biotechnology and pharmaceutical executive, experienced in product development and launch, business alliance relationships and portfolio management, as President, Diagnostics. Ms. Beggrow will lead our diagnostic initiatives, including the daily management of the breast cancer program's development team and collaboration with our key opinion leaders.

Factors Affecting our Performance

We believe that our future results of operations are dependent on several additional 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 continually working to improve the efficacy of their drug development process and the safety and efficacy of their drugs. We believe that our technology can support these initiatives by providing a seamless solution from biomarker discovery to a commercialized companion diagnostic test that can be used to assist clinicians in confidently prescribing these drugs to their patients. Our products and service solutions allow us to partner with our biopharmaceutical company customers to identify molecular biomarkers that can help determine which patients are most likely to benefit from the drug, validate these biomarkers in clinical trials and partner to commercialize the validated CDx assay. 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, including molecular profiling of respective cohorts in our VERI/O laboratory and development of custom RUO panels to support early stage clinical programs, IUO assays for clinical trials or companion diagnostic assays for approved drugs. We believe our product and service solutions provide us with a growing number of early stage programs and new opportunities to collaborate with biopharmaceutical companies in their drug development programs. Our business model is structured to allow us to capture revenue at each stage of this development lifecycle with the highest value CDx assay being the ultimate objective.

Customer Adoption of HTG Technology

Today we believe the primary measures of adoption for our technology are the number of active programs in our biopharmaceutical company customer pipeline, the number of total active customers and revenue growth relating to new and existing customers. In the future, we expect increased sales of our products and services as we add new proprietary panels to our product menu and as additional European customers adopt our existing assays or custom assays for use in clinical diagnostic testing. While our current customer mix is dominated by biopharmaceutical company customers, we expect to see growth in clinical diagnostic labs as we launch companion diagnostic assays from the above programs and as biomarker strategies are validated through our partnerships with key opinion leaders in Europe.

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 is our assay and panel menu available for use by our customers on the HTG EdgeSeq. 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 in addition to our diagnostic development strategies in immuno-oncology and next generation pathology. We will remain focused on high quality instrument placements and consumable pull through as the primary indicators of future commercial adoption and success in our business.

Timing and effectiveness of research and development expenses

Our spending on collaboration-based research and development may vary substantially from period to period due to the nature of biopharmaceutical company drug development processes and the effort involved in reaching key milestones under our companion diagnostic development agreements. Costs from our collaborative development services programs, including but not limited to the quantity of HTG EdgeSeq assay kits and instruments, third-party sequencing equipment, and third-party or internal labor required to complete development milestones, which costs are expensed to research and development expense in our consolidated statements of operations, may vary significantly from one development stage to the next. Expenses associated with our ongoing proprietary product research and development efforts are carefully managed and are standardized under our stage-gate-based new product development methodology. Program progress and priorities are assessed by time, quality and adherence to budgetary metrics at each phase of the product development.

Financial Operations Overview and Consolidated Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

	Twelve Months Ended December 31,		Change	
	2018	2017	$	%
Revenue:				
Product and product-related services	$ 9,121,390	$ 6,797,255	$2,324,135	34%
Collaborative development services	12,382,504	7,962,312	4,420,192	56%
Total revenue	21,503,894	14,759,567	6,744,327	46%
Operating expenses:				
Cost of product and product-related services revenue	5,090,475	4,971,806	118,669	2%
Selling, general and administrative	19,974,616	17,513,742	2,460,874	14%
Research and development	12,598,034	9,996,627	2,601,407	26%
Total operating expenses	37,663,125	32,482,175	5,180,950	16%
Operating loss	(16,159,231)	(17,722,608)	1,563,377	(9%)
Loss on settlement of Growth Term Loan	(105,064)	—	(105,064)	(100%)
Interest income (expense)	(186,097)	(1,234,488)	1,048,391	(85%)
Net loss before income taxes	$(16,450,392)	$(18,957,096)	$2,506,704	(13%)

Revenue

We generate revenue from two primary sources: revenue from RUO profiling for biopharmaceutical companies, academic research centers and molecular testing laboratories; and revenue from collaborative development services for biopharmaceutical companies under our companion diagnostic development programs. A developing third category of revenue is the sale of MDx products, for which our first products are in early stage commercialization in Europe but are not yet generating meaningful revenue. This revenue is included in product revenue in the accompanying consolidated statements of operations for the years ended December 31, 2018 and 2017.

RUO profiling is currently made available to our customers through product sales and service offerings. Customers can purchase our HTG EdgeSeq instrument and related consumables, which consist primarily of our proprietary molecular profiling panels and other assay components. Customers can also access our technology through contracted services. We perform these services using our HTG EdgeSeq instruments and RUO consumables to process samples in our VERI/O laboratory. Our proprietary technology is also used to develop custom RUO panels which are expected to generate future sample processing or RUO consumables revenue.

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

Total revenue increased by 46% to $21.5 million for the year ended December 31, 2018 compared with total revenue of $14.8 million for the year ended December 31, 2017. The increase in total revenue was driven by revenue generated from collaborative development services relating to our Governing Agreement, as well as increased demand for our RUO service offerings as a result of the expansion of our RUO assay menu and the continued strengthening of relationships with key biopharmaceutical company customers.

Product and product-related services revenue

Product and product-related services revenue, which includes biomarker RUO profiling revenue generated through the sale of our HTG EdgeSeq instruments and consumables and from services performed for customers in our VERI/O laboratory using our proprietary RUO technology, increased $2.3 million to $9.1 million for the year ended December 31, 2018 compared with $6.8 million for the year ended December 31, 2017, and was comprised of the following:

	Years Ended December 31,		Change	
	2018	2017	$	%
Product revenue:				
Instrument	$ 351,885	$ 385,143	(33,258)	(9%)
Consumables	1,964,499	1,463,347	501,152	34%
Total product revenue	2,316,384	1,848,490	467,894	25%
Product-related services revenue:				
Custom RUO assay design	964,241	419,515	544,726	130%
Sample processing	5,840,765	4,529,250	1,311,515	29%
Total product-related services revenue	6,805,006	4,948,765	1,856,241	38%
Total product and product-related services revenue	$9,121,390	$6,797,255	2,324,135	34%

Product revenue generated from the sale of our instruments and RUO assay kits increased 25% to $2.3 million for the year ended December 31, 2018 compared with $1.8 million for the year ended December 31, 2017, and represented 11% and 13% of our total revenue for the years ended December 31, 2018 and 2017, respectively. The increase in product revenue in 2018 compared with 2017 is primarily attributable to increased consumables product revenue generated as a result of the expansion of the menu of RUO assays that is available for purchase by the increasing number of customers who have adopted our technology in the United States and Europe.

Service revenue, consisting of sample processing using our HTG EdgeSeq instruments and consumables and custom RUO assay development, increased by $1.9 million to $6.8 million for the year ended December 31, 2018 compared with $4.9 million for the year ended December 31, 2017, and represented 32% and 34% of our total revenue for the years ended December 31, 2018 and 2017, respectively. The increase in service revenue for the year ended December 31, 2018 compared with 2017 reflects the expansion of our biopharmaceutical sales team, the menu of RUO panels, including our HTG EdgeSeq Precision Immuno-Oncology Panel, a focus on improvement of average per sample selling price and additional RUO programs using previously developed clinical trial assays for biopharmaceutical company customer studies. These customers continue to prefer to gain access to our technology through purchase of our services, which results in increased consumption of our RUO assay kits to process samples in our VERI/O laboratory. We expect our revenue mix to continue to contain a higher portion of biopharmaceutical service revenue in the near term until we enter the commercial clinical diagnostic market.

Collaborative development services revenue

Collaborative development services revenue includes services performed on biopharmaceutical company companion diagnostic development programs using our HTG EdgeSeq proprietary technology to develop, validate in clinical trials, seek regulatory approvals for and commercialize CDx assays for biopharmaceutical company therapeutics. Collaborative development services revenue, consisting of precision diagnostic program services performed for biopharmaceutical companies pursuant to our Governing Agreement with QML, increased $4.4 million to approximately $12.4 million for the year ended December 31, 2018 compared with approximately $8.0 million for the year ended December 31, 2017, and represented 58% and 54% of our total revenue for the years ended December 31, 2018 and 2017, respectively. Collaborative development services revenue for the year ended December 31, 2018 included approximately $10.2 million of monthly development fees and $2.2 million of profit sharing payments. Collaborative development services revenue for the year ended December 31, 2017 included approximately $5.7 million of monthly development fees and $2.3 million of profit sharing payments. This variability is reflective of the number of active programs in each of these periods, the amount and timing of work to be performed under each program, the timing and number of development deliverables and the timing and amount of any profit sharing payments under these agreements. Given these factors, we expect there to continue to be significant variability in the timing and amount of collaborative development services revenue recognized from one fiscal period to the next.

Cost of product and product-related services revenue

Cost of product and product-related services revenue includes product-related and services-related costs. Product-related costs include the aggregate costs incurred in manufacturing, delivering, installing and servicing instruments and consumables. The components of our product-related costs of revenue include material, subcomponent and servicing 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 service-based costs incurred in our VERI/O laboratory, include direct labor, consumables and lab supplies. Our cost of product and product-related services revenue includes fixed costs comprised primarily of manufacturing and service headcount, field service engineers, equipment and facilities. Due to the fixed nature of certain expenses, such as overhead, equipment and infrastructure, associated with our regulated industry and our expectations for further growth in

customer demand, we expect our cost of product and product-related services revenue as a percentage to decrease over time as we increase product and product-related services revenue, further absorbing these fixed costs.

Cost of product and product-related services revenue increased by 2% to $5.1 million for the year ended December 31, 2018 compared with $5.0 million for the year ended December 31, 2017. This increase reflects the increase in product and product-related services revenue from 2017 to 2018. While cost increased year over year, it increased at a lower percentage than product and product-related services revenue, reflecting higher average prices per sample for our sample processing services as well as further absorption of our fixed operating expenses, which were incurred in the expansion of our VERI/O laboratory staffing, facilities and equipment to accommodate increased demand for services.

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 $2.5 million to $20.0 million for the year ended December 31, 2018 compared with $17.5 million for the year ended December 31, 2017. The increase in our selling, general and administrative expenses are primarily due to compensation expenses including issuance of 259,551 shares of executive officer RSUs at a grant date fair value of $3.84 per share, resulting in approximately $1.0 million of additional non-cash, stock-based compensation expense for the year ended December 31, 2018. In addition, the hiring of additional biopharmaceutical sales personnel and commercialization efforts relating to our CE/IVD products in Europe, including the formation of HTG France and the buildout of an applications lab in France in the fourth quarter of 2018, further increased in selling, general and administrative expenses for the year ended December 31, 2018.

Research and development expenses

Research and development expenses represent amounts incurred to perform collaborative development services, 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, facilities and equipment. Research and development costs are expensed as incurred. Research and development expenses increased by $2.6 million to $12.6 million for the year ended December 31, 2018 compared with $10.0 million for the year ended December 31, 2017. This increase is primarily due to collaborative development costs associated with biopharmaceutical customer companion diagnostic development programs initiated in 2017 under our Governing Agreement with QML, which costs are included in research and development expense in our consolidated statements of operations as the contracts are accounted for under the FASB's guidance for collaborative arrangements. Costs relating to our collaborative development services revenue were approximately $8.0 million for the year ended December 31, 2018 compared with $4.8 million for the year ended December 31, 2017. We expect research and development costs to continue to increase in 2019 as we expand our consumable product menu and begin development of our diagnostic breast panel.

Interest income (expense)

As of December 31, 2018, we had an obligation due to NuvoGen in the amount of $7.0 million under an asset purchase agreement, a MidCap Term Loan obligation of $6.7 million, net of discount and deferred financing costs and a $3.0 million convertible debt liability to QNAH. Interest expense and non-cash interest expense recognized for discount, deferred financing fee amortization and final fee premium amounts relating to these obligations decreased $0.4 million to $0.9 million for the year ended December 31, 2018 as compared with $1.3 million for the year ended December 31, 2017. This year over year decrease was primarily the result of decreased term loan interest expense following the settlement of the Growth Term Loan in the first quarter 2018 and the borrowing of a smaller amount of principal under our MidCap Term Loan. Interest income included in interest income (expense) increased by $642,537 to $715,723 for the year ended December 31, 2018 as compared with $73,186 for the year ended December 31, 2017, primarily as a result of investments in short term available-for-sale securities relating to the proceeds from our January 2018 underwritten public offering.

Cash Flows for the Years Ended December 31, 2018 and 2017

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

	Years Ended December 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$(13,173,918)	$(16,572,308)
Investing activities	(23,220,435)	3,279,469
Financing activities	38,129,745	15,753,780
Effect of exchange rate on cash	(1,145)	–
Increase in cash, cash equivalents and restricted cash	$ 1,734,247	$ 2,460,941

Operating Activities

Net cash used in operating activities decreased by $3.4 million to $13.2 million compared with $16.6 million for the year ended December 31, 2017. This decrease for the year ended December 31, 2018 reflected (i) the net loss of $16.5 million and (ii) net non-cash items of $3.3 million, consisting primarily of stock-based compensation of $1.9 million and depreciation and amortization of $1.5 million.

Net cash used in operating activities for the year ended December 31, 2017 reflected (i) the net loss of $19.0 million, (ii) net non-cash items of $3.6 million, consisting primarily of stock-based compensation of $1.4 million, depreciation and amortization of $1.2 million, provision for excess inventory of $0.4 million, amortization of the discount, deferred financing costs and final payment premium on our Growth Term Loan of $0.4 million and amortization of the discount on our NuvoGen obligation of $0.2 million, and (iii) a net cash outflow from changes in balances of operating assets and liabilities of $1.2 million. This net cash outflow was due to an increase in accounts receivable attributable to our collaborative development services revenue partially offset by an increase in accrued liabilities primarily related to the accrual for our annual performance-based bonuses. The primary driver of the cash outflow from changes in balances of operating assets and liabilities was the increase in activities under SOW One and SOW Two of our QML Governing Agreement in the fourth quarter of 2017, which resulted in a significant increase in accounts receivable for monthly development fees and profit sharing payments receivable at year end for both programs.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2018 was $23.2 million compared with net cash provided by investing activities of $3.3 million for the year ended December 31, 2017. Net cash used in investing activities for the year ended December 31, 2018 consisted primarily of purchases of available-for-sale securities of $54.0 million with proceeds received from our underwritten public offering in January 2018, partially offset by the maturity of $31.7 million of the available-for-sale securities and the purchase of $0.9 million of tooling used in manufacturing, furniture and equipment for our new applications laboratory in France and other fixed assets during the year.

Net cash provided by investing activities for the year ended December 31, 2017 consisted primarily of sales, redemptions and maturities of $4.3 million of our remaining available-for-sale securities. This was partially offset by investments in laboratory sample processing and automation equipment of $1.0 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2018 was $38.1 million compared with $15.8 million for the year ended December 31, 2017. This activity for the year ended December 31, 2018 consisted primarily of $37.7 million in net proceeds from our underwritten public offering in January 2018, $6.6 million in net proceeds from our MidCap Term Loan in March 2018, and $0.6 million in net proceeds from an at-the-market offering of our common stock through our Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. (“ATM Offering”), partially offset by $6.0 million in payments on our Growth Term Loan balance and $1.0 million in quarterly payments on our NuvoGen obligation.

Net cash provided by financing activities for the year ended December 31, 2017 consisted primarily of $19.9 million in net proceeds from our ATM Offering and $3.0 million of proceeds from the QNAH Convertible Note, partially offset by $6.4 million in payments on our Growth Term Loan balance and $0.8 million in quarterly payments made on our NuvoGen obligation.

Liquidity and Capital Resources

Since our inception, our operations have primarily been financed through the issuance of our common stock, redeemable convertible preferred stock, the incurrence of debt and cash received from product sales, services revenue and other income. As of December 31, 2018, we had $31.1 million of cash, cash equivalents and short-term available-for-sale securities, and $16.8 million of debt outstanding on our MidCap Term Loan, NuvoGen, capital lease and QNAH Convertible Note obligations.

In January 2018, we offered and sold, in an underwritten public offering, 13,915,000 shares of our common stock at a price of $2.90 per share, including 1,815,000 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares. The aggregate net proceeds from the offering were approximately $37.7 million, after deducting the underwriting discounts and commissions and offering expenses.

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

LIBOR is currently scheduled to be phased out in 2021. Before LIBOR is phased out, we may need to renegotiate the MidCap Credit Facility to replace LIBOR with a new standard, which has yet to be established. The consequences of these developments cannot be entirely predicted, but could result in higher interest rates on our loans under the MidCap Credit Facility.

The MidCap Revolving Loan provides a secured revolving credit facility in an aggregate principal amount of up to $2.0 million. We may request an increase in the total commitments under the MidCap Revolving Loan by up to an additional $8.0 million, subject to agent and lender approval and the satisfaction of certain conditions. Availability of the revolving credit facility under the MidCap Revolving Loan will be based upon a borrowing base formula and periodic borrowing base certifications valuing certain of our accounts receivable and inventory, as reduced by certain reserves, if any. Though the MidCap Revolving Loan was made available upon the Company's establishment of certain lockbox arrangements in June 2018, there were no amounts outstanding under the Midcap Revolving Loan as of December 31, 2018. The proceeds of any loans under the MidCap Revolving Loan may be used for working capital and general corporate purposes.

Funding Requirements

We have had recurring operating losses and negative cash flows from operations since inception, and we had an accumulated deficit of approximately $151.0 million as of December 31, 2018. As of December 31, 2018, we had available cash, cash equivalents and investments in short-term available-for-sale securities of approximately $31.1 million and had current liabilities of approximately $7.0 million plus an additional $15.7 million in long-term liabilities primarily attributable to our MidCap Term Loan, NuvoGen obligation and QNAH Convertible Note. We believe that our existing resources will be sufficient to fund our planned operations for at least the next 12 months from the issuance of the consolidated financial statements included elsewhere in this report. However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

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

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

price that may result in up to a total loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets.

Contractual Obligations

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.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements as defined by applicable SEC regulations.

Recent Accounting Pronouncements

For a summary of recent accounting pronouncements applicable to our consolidated financial statements, see "Note 2. Basis of Presentation and Summary of Significant Accounting Policies" in Part II, Item 8, Notes to Consolidated Financial Statements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Items subject to estimates based on judgments include, but are not limited to: revenue recognition, stock-based compensation expense, the value of the warrant liability, the resolution of uncertain tax positions, income tax valuation allowances and reserves, 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 from Contracts with Customers

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

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

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

Product and Product-related Services Revenue

Sale of instruments and consumables

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

customer has the ability to use the instrument and has accepted the asset. Installation generally occurs within one month of instrument shipment.

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

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

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

We provide instruments to certain customers under reagent rental agreements. Under these agreements, an instrument is installed 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. We measure progress toward complete satisfaction of this performance obligation to provide the instrument and deliver the consumables using an output method based on the number of consumables delivered in relation to the total consumables to be provided under the reagent rental agreement. This is considered to be representative of the delivery of outputs under the arrangement and the best measure of progress because the customer benefits from the instrument only in conjunction with the consumables. We expect 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, we retain title to the instrument and title is transferred to the customer at no additional charge at the conclusion of the initial arrangement. The cost of the instrument is amortized on a straight-line basis over the term of the arrangement, unless there is no minimum consumable product purchase, in which case the instrument would be expensed as cost of product and product-related services revenue upon installation. Cost to maintain the instrument while we hold title is charged to selling, general and administrative expense as incurred.

Service revenue

Sample Processing Services

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

Custom RUO Assay Development

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

Collaborative Development Services

We follow ASC 606, Revenue from Contracts with Customers and ASC 808, Collaborative Arrangements to determine the appropriate recognition of revenue under our collaborative research, development and commercialization agreements that contain multiple elements. We have determined that SOW One, SOW Two and SOW Three are collaborative arrangements and that QML meets the definition of a customer under ASC 606. Additionally, each SOW is a separate contract with a single performance obligation to provide development services. Under each SOW, QML pays a monthly fee for development work performed by us and our subcontractors. The monthly fee is based on the employee and materials costs incurred during the month, which is subject to significant variability from period to period and unknown until the costs are incurred. Therefore, the monthly fee, which is based on use of hours and costs as a measure of progress, is included in the transaction price and recognized as revenue over time when the costs are incurred and the monthly fee is billed to QML. As we have the right to consideration from the customer in an amount that corresponds directly to the value to the customer of our performance completed to date, we recognize revenue in the amount to which we have the right to invoice. It is at this time that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. We also share any net profits resulting from performance of the development work with QML as determined pursuant to the Governing Agreement. Such profit sharing payment(s) is deemed to be variable consideration using the expected value method and is included in the transaction price upon completion of the respective SOW deliverables, acceptance of corresponding deliverables, and the mutual agreement by both parties on the calculation of net profit, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

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

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 consolidated 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 and high credit quality corporate debt securities classified as available-for-sale securities.

Inventory Valuation

Inventory consists of raw materials and finished goods which are stated at the lower of cost (first-in, first-out) or net realizable value. 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 under our equity incentive plans of stock options and restricted stock units ("RSUs") and stock purchase rights granted under our ESPP, based on the estimated fair value of the awards on the date of grant. The fair value of RSUs is based on the quoted market price of our common stock on the date of grant. We do not estimate the number of awards expected to be forfeited but instead we account for them as they occur. 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 could significantly impact the compensation expense that has been recognized in our consolidated 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.

Foreign Currency Translation and Foreign Currency Transactions

We have assets and liabilities, including accounts receivable and accounts payable, which are denominated in currencies other than our functional currency. These balance sheet items are subject to re-measurement, the impact of which is recorded in foreign currency gain (loss) within the consolidated statements of operations.

Adjustments resulting from translating foreign functional currency financial statements of our wholly owned subsidiary into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive loss in the accompanying consolidated statements of stockholder's equity (deficit).

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 an insufficient history of operating profits, 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, 2018 and 2017, we have provided a full valuation allowance for all net deferred tax assets due to their current realization being considered remote. 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 Tax Act, which was signed into law on December 22, 2017, significantly revised the IRC. For further information as to its impact on our financial statements see "Note 15. Income Taxes" in Part II, Item 8, Notes to Financial Statements.

Emerging Growth Company Status

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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 8. Consolidated Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of HTG Molecular Diagnostics, Inc. (the "Company") and subsidiary as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiary at December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2014.

Phoenix, Arizona
March 7, 2019

HTG Molecular Diagnostics, Inc.
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 8,432,600	$ 9,968,600
Short-term investments available-for-sale, at fair value	22,681,049	—
Accounts receivable	5,012,678	6,356,268
Inventory, net of allowance of $39,403 and $62,142 at December 31, 2018 and 2017, respectively	1,306,609	1,180,521
Prepaid expenses and other	568,209	443,068
Total current assets	38,001,145	17,948,457
Restricted cash - non-current	3,270,247	—
Deferred offering costs	59,030	2,953
Deferred MidCap revolving loan costs	67,068	—
Property and equipment, net	2,373,790	3,304,890
Total assets	$ 43,771,280	$ 21,256,300
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,849,921	$ 2,438,798
Accrued liabilities	3,358,465	3,746,786
Contract liabilities - current	332,711	665,882
NuvoGen obligation - current	1,290,234	496,442
Growth Term Loan payable - net of discount and debt issuance costs	—	5,793,599
Other current liabilities	186,043	200,460
Total current liabilities	7,017,374	13,341,967
NuvoGen obligation - non-current, net of discount	5,702,519	7,520,913
Convertible note, related party - net of debt issuance costs	2,974,213	2,960,760
MidCap Term Loan payable - net of discount and debt issuance costs	6,704,641	—
Other non-current liabilities	280,471	492,197
Total liabilities	22,679,218	24,315,837
Commitments and Contingencies (Note 14)		
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2018 and December 31, 2017, 28,585,449 shares issued and outstanding at December 31, 2018 and 13,929,763 shares issued and outstanding at December 31, 2017	28,585	13,929
Additional paid-in-capital	172,086,909	131,492,595
Accumulated other comprehensive loss	(3,453)	—
Accumulated deficit	(151,019,979)	(134,566,061)
Total stockholders' equity (deficit)	21,092,062	(3,059,537)
Total liabilities and stockholders' equity (deficit)	$ 43,771,280	$ 21,256,300

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

HTG Molecular Diagnostics, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2018	**2017**
Revenue:		
Product and product-related services	$ 9,121,390	$ 6,797,255
Collaborative development services	12,382,504	7,962,312
Total revenue	21,503,894	14,759,567
Operating expenses:		
Cost of product and product-related services revenue	5,090,475	4,971,806
Selling, general and administrative	19,974,616	17,513,742
Research and development	12,598,034	9,996,627
Total operating expenses	37,663,125	32,482,175
Operating loss	(16,159,231)	(17,722,608)
Other income (expense):		
Interest expense	(901,820)	(1,307,674)
Interest income	715,723	73,186
Loss on extinguishment of Growth Term Loan	(105,064)	—
Total other income (expense)	(291,161)	(1,234,488)
Net loss before income taxes	(16,450,392)	(18,957,096)
Provision for income taxes	3,526	2,921
Net loss	$ (16,453,918)	$ (18,960,017)
Net loss per share, basic and diluted	$ (0.60)	$ (1.79)
Shares used in computing net loss per share, basic and diluted	27,523,463	10,597,318

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

HTG Molecular Diagnostics, Inc.
Consolidated Statements of Comprehensive Loss

	Years Ended December 31,	
	2018	2017
Net loss	$ (16,453,918)	$ (18,960,017)
Other comprehensive income (loss), net of tax effect:		
Unrealized gain (loss) on short-term investments	(2,308)	1,090
Foreign currency translation adjustment	(1,145)	—
Total other comprehensive income (loss)	(3,453)	1,090
Comprehensive loss	$ (16,457,371)	$ (18,958,927)

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

HTG Molecular Diagnostics, Inc.
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at January 1, 2017	7,938,571	$ 7,938	$110,081,334	$ (75,000)	$ (1,090)	$(115,606,044)	$ (5,592,862)
Exercise of stock options	41,815	42	112,096	—	—	—	112,138
Stock-based compensation expense	—	—	1,376,633	—	—	—	1,376,633
Release of restricted stock awards	336,333	336	—	—	—	—	336
Stock issued under stock purchase plan	141,082	141	325,526	—	—	—	325,667
Issuance of common stock from ATM offering, net of issuance costs of $0.8 million	5,471,962	5,472	19,672,006	—			19,677,478
Retirement of Treasury shares	—	—	(75,000)	75,000	—	—	—
Net loss	—	—	—	—	—	(18,960,017)	(18,960,017)
Unrealized gain on short-term investments	—	—	—	—	1,090	—	1,090
Balance at December 31, 2017	13,929,763	$ 13,929	$131,492,595	$ —	$ —	$(134,566,061)	$ (3,059,537)
Exercise of stock options	144,645	145	316,622	—	—	—	316,767
Stock-based compensation expense	—	—	1,887,764	—	—	—	1,887,764
Release of restricted stock awards	291,010	291	—	—	—	—	291
Net share settlement of restricted stock awards	(38,582)	(39)	(150,709)	—	—	—	(150,748)
Stock issued under stock purchase plans	82,261	82	199,792	—	—	—	199,874
Issuance of common stock from ATM offering, net of issuance costs of approximately $17,000	261,352	262	556,444	—	—	—	556,706
Issuance of common stock from underwritten public offering, net of issuance costs of approximately $2.6 million	13,915,000	13,915	37,710,401	—	—	—	37,724,316
Issuance of common stock warrants in connection with MidCap Term Loan	—	—	74,000	—	—	—	74,000
Net loss	—	—	—	—	—	(16,453,918)	(16,453,918)
Unrealized loss on short-term investments	—	—	—	—	(2,308)	—	(2,308)
Foreign currency translation adjustment	—	—	—	—	(1,145)	—	(1,145)
Balance at December 31, 2018	28,585,449	$ 28,585	$172,086,909	$ —	$ (3,453)	$(151,019,979)	$ 21,092,062

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

HTG Molecular Diagnostics, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2018	2017
Operating activities		
Net loss	$ (16,453,918)	$ (18,960,017)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,468,121	1,241,873
Accretion of discount on NuvoGen obligation	(12,480)	195,248
Provision for excess inventory	83,218	366,963
Amortization of Growth Term Loan discount and issuance costs	62,951	404,462
Loss on extinguishment of Growth Term Loan	105,064	—
Amortization of QNAH Convertible Note issuance costs	13,453	1,269
Amortization of MidCap Credit Facility discount and issuance costs	133,963	—
Stock-based compensation expense	1,888,055	1,376,969
Employee stock purchase plan expense	58,959	59,118
Accretion of incentive from landlord	(142,000)	(142,000)
Accrued interest on available-for-sale securities investments	(412,436)	—
Loss on disposal of assets	8,104	81,539
Changes in operating assets and liabilities:		
Accounts receivable	1,332,030	(4,978,827)
Inventory	(171,909)	77,176
Prepaid expenses and other	(113,581)	(3,749)
Deferred offering costs	2,953	49,630
Accounts payable	(150,176)	1,225,954
Accrued liabilities	(447,351)	2,076,500
Contract liabilities	(426,938)	355,584
Net cash used in operating activities	(13,173,918)	(16,572,308)
Investing activities		
Purchase of property and equipment	(949,514)	(1,020,531)
Sales, redemptions and maturities of available-for-sale securities	31,700,000	4,300,000
Purchase of available-for-sale securities	(53,970,921)	—
Net cash (used in) provided by investing activities	(23,220,435)	3,279,469
Financing activities		
Proceeds from MidCap Credit Facility	7,000,000	—
MidCap Credit Facility lender fees	(422,390)	—
Payments on Growth Term Loan	(1,684,626)	(6,389,782)
Payments for extinguishment of Growth Term Loan	(4,276,988)	—
Proceeds from public offering, net of underwriting discounts, commissions and costs of $2.6 million	37,724,316	(231,476)
Proceeds from ATM Offering, net	556,706	19,908,954
Proceeds from issuance of convertible note to QNAH, a related party	—	3,000,000
QNAH Convertible Note financing costs	—	(40,509)
Payments on NuvoGen obligation	(1,012,122)	(800,000)
Payments on capital leases	(62,085)	(69,142)
Proceeds from exercise of stock options	316,767	112,138
Taxes paid for net share settlement of restricted stock awards	140,915	—
Proceeds from shares purchased under stock purchase plans	—	266,549
Payment of deferred offering costs	(150,748)	(2,952)
Net cash provided by financing activities	38,129,745	15,753,780
Effect of exchange rates on cash	(1,145)	—
Increase in cash, cash equivalents and restricted cash	1,734,247	2,460,941
Cash and cash equivalents at beginning of year	9,968,600	7,507,659
Cash, cash equivalents and restricted cash at end of year	$ 11,702,847	$ 9,968,600
Supplemental disclosure of noncash investing and financing activities		
Fixed asset purchases payable and accrued at period end	$ 39,265	$ 477,966
Carrying value of demonstration units transferred from property and equipment to inventory	49,245	113,607
Equipment purchased through capital lease	71,709	—
Debt issuance costs payable and accrued at period end	59,030	—
MidCap Term Loan fees and warrant discount	389,000	—
Retirement of treasury stock	—	75,000
Supplemental cash flow information		
Cash paid for interest	$ 553,070	$ 698,065
Cash paid for taxes	3,545	1,967

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

Note 1. Description of Business, Basis of Presentation and Principles of Consolidation

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

The Company operates in one segment and its customers are located primarily in the United States and Europe. For the year ended December 31, 2018, approximately 69% of the Company's revenue was generated from sales originated by customers located outside of the United States, compared with 71% for the year ended December 31, 2017. Approximately 84% and 76% of the sales to customers located outside of the United States resulted from collaborative development services revenue generated from the Master Assay Development, Commercialization and Manufacturing Agreement (the "Governing Agreement"), with QIAGEN Manchester Limited ("QML"), a wholly owned subsidiary of QIAGEN N.V. (See Note 16), for the years ended December 31, 2018 and 2017, respectively.

Basis of Presentation

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

Principles of Consolidation

The Company formed a French subsidiary, HTG Molecular Diagnostics France SARL ("HTG France"), in November 2018. The consolidated financial statements include the accounts of the Company and this wholly owned subsidiary after elimination of intercompany transactions and balances as of December 31, 2018.

Reclassifications

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

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The Company's significant estimates include revenue recognition, stock-based compensation expense, bonus accrual, income tax valuation allowances and reserves, recovery of long-lived assets, 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 an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with financial institutions, commercial paper, 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.

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 accompanying consolidated 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 accompanying consolidated 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).

Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the accompanying consolidated balance sheets that sum to the total of the same such amounts shown in the accompanying consolidated statements of cash flows.

	December 31, 2018
Cash and cash equivalents	$ 8,432,600
Restricted cash - non-current	3,270,247
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 11,702,847

Amounts included in restricted cash represent those required to be set aside in escrow under the terms of the MidCap Term Loan (see Note 8) to collateralize the payment that will be due upon maturity of the QNAH Convertible Note (see Note 16). The amounts will be released to the Company upon subsequent delivery of subordination documents for the QNAH Convertible Note to MidCap or conversion of the QNAH Convertible Note. If neither occurs, the amounts will be applied by the escrow agent to repay in full the QNAH Convertible Note at maturity (or in connection with a prepayment at the direction of the Company) subject to the terms of the MidCap Term Loan.

Contract Assets

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

Fair Value of Financial Instruments

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.

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 value of the MidCap Term Loan (see Note 8) is estimated to approximate its fair value as the interest rate approximates the market rate for debt securities with similar terms and risk characteristics.

In October 2017, the Company received $3.0 million in gross proceeds from, and issued a subordinated convertible promissory note (the "QNAH Convertible Note") in that principal amount to, QIAGEN North American Holdings, Inc. ("QNAH"). As of December 31, 2018, the estimated aggregate fair value of the QNAH Convertible Note is approximately $3.1 million, based on a discounted cash flow approach and utilizing an option pricing model to value the conversion feature, with key assumptions including expected volatility, discount rates, term and risk-free rates.

The NuvoGen obligation is an obligation relating to an asset purchase transaction with a then-common stockholder of the Company. As of December 31, 2018, the estimated aggregate fair value of the NuvoGen obligation is approximately $6.0 million, determined using a Monte Carlo simulation with key assumptions including future revenue, volatility, discount and risk-free rates.

The estimated fair values of the QNAH Convertible Note and the NuvoGen obligation represent Level 3 measurements.

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 net realizable value. Cost is determined using a standard cost system, whereby the standard costs are updated periodically to reflect current costs and net realizable value 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.

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 the product 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 accompanying consolidated statements 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, 2018 was $143,271 compared to $53,365 as of December 31, 2017.

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. Equipment used in the field is amortized using the straight-line method over the lesser of the period of the related reagent rental or collaborative development services agreement where applicable 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 in the consolidated balance sheets as of December 31, 2018. 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 consolidated balance sheets and is being accreted over the lease term as a reduction of rent expense (see Note 14).

Costs incurred in the development and installation of software for internal use and in the development of the Company's website 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.

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, 2018 and 2017.

Debt Issuance Costs and Debt Discounts

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

Deferred Offering Costs

Deferred offering costs represent legal and other direct costs related to planned future stock offering transactions. Deferred offering costs of $59,030 included as non-current assets in the accompanying consolidated balance sheets represent legal costs incurred during the year ended December 31, 2018 by the Company in contemplation of the issuance of additional shares in a future financing transaction. There were deferred offering costs of $2,953 included in the accompanying consolidated balance sheets as of December 31, 2017. Should the planned stock offering transactions prove to be unsuccessful, these deferred offering costs, as well as any additional expenses to be incurred, will be charged to selling, general and administrative expense in the consolidated statements of operations.

Contract Liabilities

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

Revenue Recognition

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

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

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

See Note 9 for additional discussion of the Company's revenue recognition policies.

Product Warranty

The Company generally provides a one-year warranty on its HTG EdgeSeq systems covering the performance of system hardware and software in conformance with customer specifications under normal use and protecting against defects in materials and workmanship. The Company may, at its option, replace, repair or exchange products covered under valid warranty claims. A provision for estimated warranty costs is recognized at the time of sale, through cost of product and product-related services revenue, based upon recent historical experience and other relevant information as it becomes available. The Company continuously assesses the adequacy of its product warranty accrual by reviewing actual claims and adjusts the provision as needed.

Research and Development Expenses

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

Advertising

All costs associated with advertising and promotions are expensed as incurred. Advertising expense was $110,591 and $245 for the years ended December 31, 2018 and 2017, respectively, and is included as a component of selling, general and administrative expenses on the accompanying consolidated statements of operations.

Stock-based Compensation

The Company incurs stock-based compensation expense relating to grants under its equity incentive plans of restricted stock units ("RSUs") and stock options to employees, consultants and non-employee directors, and stock purchase rights granted under 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 elected to change its policy surrounding forfeitures of equity awards with the adoption of the guidance in ASU No. 2016-09 on January 1, 2017. The Company no longer estimates the number of awards expected to be forfeited but instead accounts for such forfeitures as they occur.

For stock-based awards 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 each award is remeasured at each measurement date until performance by the nonemployee 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. 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 an insufficient history of operating profits, 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, 2018 and 2017, 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. The Tax Cuts and Jobs Act (the "Tax Act"), which was signed into law on December 22, 2017, significantly revised the Internal Revenue Code of 1986, as amended (the "IRC"). For further information as to its impact on our financial statements see "Note 15. Income Taxes" in Part II, Item 8, Notes to Financial Statements.

Foreign Currency Translation and Foreign Currency Transactions

The Company has assets and liabilities, including accounts receivable and accounts payable, which are denominated in currencies other than its functional currency. These balance sheet items are subject to re-measurement, the impact of which is recorded in foreign currency gain (loss) within the consolidated statements of operations.

Adjustments resulting from translating foreign functional currency financial statements of the Company's wholly owned subsidiary into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive loss in the accompanying consolidated statements of stockholder's equity (deficit).

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 and adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars 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 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 RUO panel design and collaborative development services primarily to biopharmaceutical companies, academic institutions and molecular labs. The Company routinely assesses the financial strength of its customers and credit losses have been minimal to date.

The top three customers accounted for 58%, 10% and 9% of the Company's revenue for the year ended December 31, 2018, compared with 54%, 8% and 6% for the year ended December 31, 2017. The largest three customers accounted for approximately 44%, 27%, and 11% of the Company's net accounts receivable as of December 31, 2018. The accounts receivable primarily relate to sample processing services performed for two biopharmaceutical company customers and work performed under the Company's Governing Agreement with QML. The largest two customers accounted for approximately 66% and 11% of the Company's net accounts receivable at December 31, 2017.

Three vendors accounted for 24%, 14% and 11% of the Company's accounts payable as of December 31, 2018 primarily related to the Company's collaborative development services programs compared to 23%, 17% and 15% of the Company's accounts payable at December 31, 2017.

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

Recently Adopted Accounting Pronouncements

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

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

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

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

The new revenue standard and the standards that amend it were effective for public entities for fiscal years and interim periods within those fiscal years beginning after December 15, 2017, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company adopted ASC 606 as of January 1, 2018 using the full retrospective approach. The adoption of ASC 606 did not have a material impact on 2017 revenue recognition or on opening equity, as the timing and measurement of revenue recognition is materially the same for the Company as under ASC 605, *Revenue Recognition*. The Company has presented additional quantitative and qualitative disclosures regarding identified revenue streams and performance obligations beginning with the first quarter ended March 31, 2018 (see Note 9 and Note 16). The Company has also identified and implemented changes to its business processes and internal controls relating to implementation of the new standard.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"), which will impact certain aspects of recognition, measurement, presentation and disclosure of financial instruments. In February 2018, the FASB subsequently issued ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments – Overall, which clarified certain aspects of the previously issued ASU 2016-01. The new guidance requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the consolidated financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. The Company adopted ASU 2016-01 as of January 1, 2018, at which time the standard did not have a significant impact on its consolidated financial statements.

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

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash or restricted cash equivalents are to be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments to this update were effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2017. The Company adopted ASU No. 2016-18 as of January 1, 2018, however the adoption of this update did not have an impact on the Company's consolidated financial statements until the quarter ended September 30, 2018, when the Company first recorded a restricted cash balance related to the QML Convertible Note.

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

New Accounting Pronouncements

The following are new FASB ASUs that had not been adopted by the Company as of December 31, 2018, and are grouped by their respective effective dates:

January 1, 2019

In February 2016, the FASB issued ASU No. 2016-02, *Leases,* which was subsequently amended by ASU No. 2018-01, ASU No. 2018-10 and ASU No. 2018-11 (collectively, "ASC 842"). Under this standard, which applies to both lessors and lessees, lessees will be required to recognize all leases (except for short-term leases) as a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and as a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements, with certain practical expedients available. The Company has completed its review of all lease contracts that were in place as of December 31, 2018 and is finalizing the calculations of the right-of-use asset and related disclosures. Based upon assessment of the Company's leases, adoption of ASC 842 is not expected to have a material effect on the Company's consolidated statements of operations, its consolidated statements of cash flows or its opening equity. However, the Company estimates that adoption of the new standard will result in a gross-up on its consolidated balance sheets of less than $1.5 million as of January 1, 2019 relating to office and equipment leases. The Company will present additional quantitative and qualitative disclosures regarding its lease obligations as required upon implementation of ASC 842 and has identified and is implementing changes to its business processes and internal controls relating to implementation of the new standard.

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

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting*. The standard expands the scope of Topic 718 to include share-based payments issued to nonemployees for goods or services, simplifying the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years with early adoption permitted, including adoption in an interim period. The Company does not believe the adoption of this standard will have a significant impact on its consolidated financial statements given the limited number of nonemployee stock-based awards outstanding.

January 1, 2020

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses*, which was subsequently amended by ASU 2018-19, requires the measurement of expected credit losses for financial instruments carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. Early adoption is permitted for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. The Company does not believe the adoption of this standard will have a significant impact on its consolidated 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 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement against or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, which amended ASC 808, *Collaborative Arrangements* and ASC 606, *Revenue from Contracts with Customers* ("ASU 2018-18"), to require that transactions in collaborative arrangements be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. The amendments also preclude entities from presenting consideration from transactions with a collaborator that is not a customer together with revenue recognized from contracts with customers. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. Early adoption is permitted, including in any interim period, provided an entity has already adopted ASC 606 or does so concurrently with the adoption of this guidance. The Company is currently evaluating the impact of its pending adoption of ASU 2018-18 on its consolidated financial statements.

Note 3. Inventory

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

	December 31,	
	2018	2017
Raw materials	$ 892,631	$ 984,328
Work in process	168,937	66,314
Finished goods	284,444	192,021
Total gross inventory	1,346,012	1,242,663
Less inventory allowance	(39,403)	(62,142)
	$ 1,306,609	$ 1,180,521

The reserve for shrinkage and excess inventory was $39,403 and $62,142 as of December 31, 2018 and 2017, respectively. For the year ended December 31, 2018, the Company recorded a net decrease in the inventory reserve of $22,739, compared to a net decrease of $208,165 for the year ended December 31, 2017, to adjust for estimated shrinkage and obsolescence. For the years ended December 31, 2018 and 2017, the Company recorded adjustments to the provision for excess inventory of $83,218 and $366,963, respectively. Adjustments in these periods to the allowance for estimated shrinkage, obsolescence and excess inventory have been included in cost of product and product-related services revenue in the accompanying consolidated statements of operations.

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, 2018 and 2017, respectively, in the fair value hierarchy:

	Balance at December 31, 2018			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 6,923,255	$ 998,400	$ —	$ 7,921,655
Investments available-for-sale at fair value				
U.S. government obligations	6,031,515	—	—	6,031,515
Corporate debt securities	—	16,649,534	—	16,649,534
Total	$12,954,770	$17,647,934	$ —	$30,602,704

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

There 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, 2018 and 2017.

Level 1 instruments include investments in money market funds, U.S. Treasuries and U.S. government agency obligations. These instruments are valued using quoted market prices for identical unrestricted instruments in active markets. The Company defines active markets for debt instruments based on both the average daily trading volume and the number of days with trading activity. Level 2 instruments include corporate debt securities and commercial paper. 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, 2018 or 2017 and did not have any Level 3 financial assets or liabilities during either of these periods.

Note 5. Available-for-Sale Securities

The Company's portfolio of available-for-sale securities consists of U.S. Treasuries and high credit quality corporate debt securities. The following is a summary of the Company's available-for-sale securities at December 31, 2018:

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
U.S. Treasury securities	$ 6,032,844	$ —	$ (1,329)	$ 6,031,515
Corporate debt securities	16,650,513	—	(979)	16,649,534
Total available-for-sale securities	$22,683,357	$ —	$ (2,308)	$22,681,049

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

The net adjustment to unrealized holding gains (losses) on available-for-sale securities, net of tax in other comprehensive income totaled $(2,308) and $1,090 for the years ended December 31, 2018 and 2017, respectively.

Contractual maturities of debt investment securities at December 31, 2018 are shown below. Expected maturities will differ from contractual maturities because the issuers of the securities may have the right to prepay obligations without prepayment penalties.

	Under 1 Year	1 to 2 Years	Total
U.S. Treasury securities	$ 6,031,515	$ —	$ 6,031,515
Corporate debt securities	16,649,534	—	16,649,534
Total available-for-sale securities	$22,681,049	$ —	$22,681,049

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, 2018:

	Under 1 Year		1 to 2 Years		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. Treasury securities	$6,031,515	$ (1,329)	$ —	$ —	$6,031,515	$ (1,329)
Corporate debt securities	1,201,308	(979)	—	—	1,201,308	(979)
Total available-for-sale securities with unrealized losses	$7,232,823	$ (2,308)	$ —	$ —	$7,232,823	$ (2,308)

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

Note 6. Property and Equipment

Property and equipment, net consists of the following:

	December 31,	
	2018	2017
Furniture & fixtures	$ 791,973	$ 582,007
Leasehold improvements	1,930,300	1,863,698
Equipment used in manufacturing	2,297,797	1,963,558
Equipment used in research & development	1,456,954	1,328,556
Equipment used in the field	125,253	130,552
Software	373,683	373,683
Construction in progress	19,246	255,641
	6,995,206	6,497,695
Less: accumulated depreciation and amortization	(4,621,416)	(3,192,805)
	$ 2,373,790	$ 3,304,890

Depreciation and leasehold improvement amortization expense was $1,468,121 for the year ended December 31, 2018, and $1,241,873 for the year ended December 31, 2017.

Note 7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2018	2017
Accrued employee bonuses	$ 2,150,418	$ 3,049,109
Payroll and employee benefit accruals	698,969	369,275
Accrued professional fees	60,400	101,150
Accrued interest	156,492	45,544
Other accrued liabilities	292,186	181,708
	$ 3,358,465	$ 3,746,786

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 bore interest at fixed rates of 8.5% and 8.75% per annum, respectively, and were scheduled to mature in September 2018. The amended agreement also included a prepayment fee of 1% of the principal amount repaid if the Growth Term Loan was repaid after the second anniversary of the August 2015 amendment and prior to maturity.

The Company recognized approximately $629,777 of debt discount associated with the Growth Term Loan A and Growth Term Loan B in the accompanying consolidated balance sheets as of December 31, 2017, resulting from unamortized direct loan costs, warrant allocation and the final payment fee. The debt discount was being amortized to interest expense using the effective interest method, over the term of the related Growth Term Loan tranche. The aggregate amortization of debt discount associated with the Growth Term Loan was approximately $62,951 and $404,462 for the years ended December 31, 2018 and 2017, respectively.

Extinguishment of Growth Term Loan upon MidCap Credit Facility Closing

In March 2018, the Company repaid all principal and interest amounts outstanding under the Growth Term Loan in an aggregate amount equal to approximately $4.3 million, including collateral agent legal fees and prepayment fees. The repayment was funded with net proceeds from the MidCap Credit Facility (see description of the MidCap Credit Facility below). As a result of the repayment, the Company recorded a loss on extinguishment of the Growth Term Loan of $105,064, including remaining unamortized discounts of $67,272 and prepayment and other Growth Term Loan lender fees in the accompanying consolidated statements of operations for the year ended December 31, 2018. All obligations under the Growth Term Loan were terminated upon extinguishment of the Growth Term Loan.

MidCap Credit Facility

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

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

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

MidCap Tranche 1, and if borrowed, MidCap Tranche 2, each bear interest at a floating rate equal to 7.25% per annum, plus the greater of (i) 1.25% or (ii) the one-month LIBOR. Interest on each term loan advance is due and payable monthly in arrears and was calculated at a rate of 9.6% for interest accrued as of December 31, 2018. Principal on each term loan advance is payable in 36 equal monthly installments beginning April 1, 2020 until paid in full on March 1, 2023. Prepayments of the term loans under the MidCap Term Loan, in whole or in part, will be subject to early termination fees in an amount equal to 3.0% of principal prepaid if prepayment occurs on or prior to the first anniversary of the MidCap Closing Date, 2.0% of principal prepaid if prepayment occurs after the first anniversary of the MidCap Closing Date but on or prior to the second anniversary of the MidCap Closing Date, and 1.0% of principal prepaid if prepayment occurs after the second anniversary of the MidCap Closing Date and prior to or on the third anniversary of the MidCap Closing Date. In connection with execution of the MidCap Term Loan, the Company paid MidCap a $100,000 origination fee.

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

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

The MidCap Revolving Loan provides a secured revolving credit facility in an aggregate principal amount of up to $2.0 million. The Company may request an increase in the total commitments under the MidCap Revolving Loan by up to an additional $8.0 million, subject to agent and lender approval and the satisfaction of certain conditions. Availability of the revolving credit facility under the MidCap Revolving Loan will be based upon a borrowing base formula and periodic borrowing base certifications valuing certain of the Company's accounts receivable and inventory, as reduced by certain reserves, if any. Further, although the revolving credit facility was made available following establishment of required lockbox arrangements by the Company in June 2018, there were no amounts outstanding under the MidCap Revolving Loan as of December 31, 2018. The proceeds of any loans under the MidCap Revolving Loan may be used for working capital and general corporate purposes.

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

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

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

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

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

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

The Company has recognized approximately $610,359 of unamortized debt discount associated with the MidCap Term Loan, resulting from fees and debt issuance costs, in the accompanying consolidated balance sheets as of December 31, 2018. Amortization of the debt discount associated with the MidCap Term Loan was approximately $121,611 for the year ended December 31, 2018 and was included in interest expense in the accompanying consolidated statements of operations. Unamortized costs incurred in connection with the issuance of the Midcap Revolving Loan of $67,068 as of December 31, 2018 are presented as deferred MidCap revolving loan costs in the accompanying consolidated balance sheets. Amortization of deferred MidCap revolving loan costs was $12,352 for the year ended December 31, 2018, and is included in interest expense in the accompanying consolidated statements of operations. There were no costs associated with the MidCap Term Loan or the MidCap Revolving Loan for the year ended December 31, 2017.

Other Debt Obligations to Related Parties

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

Note 9. Revenue from Contracts with Customers

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

Product and Product-related Services Revenue

The Company had product and product-related services revenue consisting of revenue from the sale of instruments and consumables and the use of the HTG EdgeSeq proprietary technology to process samples and design custom RUO assays for the years ended December 31, 2018 and 2017 as follows:

	Years Ended December 31,	
	2018	2017
Product revenue:		
Instrument	$ 351,885	$ 385,143
Consumables	1,964,499	1,463,347
Total product revenue	2,316,384	1,848,490
Product-related services revenue:		
Custom RUO assay design	964,241	419,515
Sample processing	5,840,765	4,529,250
Total product-related services revenue	6,805,006	4,948,765
Total product and product-related services revenue	$ 9,121,390	$ 6,797,255

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

Sale of instruments and consumables

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

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

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

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

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

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

Service Revenue

Sample Processing

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

Custom RUO Assay Design and Related Agreements

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

Collaborative Development Services Revenue

	Years Ended December 31,	
	2018	2017
Collaborative development services	$ 12,382,504	$ 7,962,312

See Note 16 for discussion of collaborative development services contracts with related parties. There was $0 and $25,000 of collaborative development services revenue generated from the Company's companion diagnostic development services agreements with non-related party customers for the years ended December 31, 2018 and 2017, respectively.

Contract Liabilities

The Company receives up-front payments from customers for custom RUO assay design services, and occasionally for sample processing services. Payments for instrument extended warranty contracts are made in advance as are payments for certain agreed-upon capital purchases required for collaborative development service projects. The Company recognizes such up-front payments as a contract liability. The contract liability is subsequently reduced at the point in time that the data file is delivered for sample processing services or as the Company satisfies its performance obligations over time for RUO assay design, collaborative development and extended warranty services. Contract liabilities of $410,947 and $837,885 were included in contract liabilities – current and other non-current liabilities in the accompanying consolidated balance sheets as of December 31, 2018 and 2017, respectively.

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

	Product Revenue	Custom RUO Assay Design	Sample Processing	Collaborative Development Services	Total Contract Liability
Balance at January 1, 2018	$ 39,426	$ 197,606	$ 490,536	$ 110,317	$ 837,885
Deferral of revenue	190,703	448,580	197,541	70,918	907,742
Customer deposits	131,864	—	—	—	131,864
Recognition of deferred Revenue	(245,446)	(596,186)	(443,677)	(181,235)	(1,466,544)
Balance at December 31, 2018	$ 116,547	$ 50,000	$ 244,400	$ —	$ 410,947

Note 10. 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 the greater of $400,000 annually, in quarterly installments, or 6% of its yearly revenue, which percentage payment would be reduced by any fixed payment installments made during the applicable period, 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 paid yearly fixed fees, in quarterly installments, to NuvoGen of $400,000 and $800,000 for the years ended December 31, 2018 and 2017, respectively. Although the amendment allowed for the deferral of any revenue-based payments through December 31, 2017, no revenue-based payments have been deferred, and additional revenue-based payments of $363,686 and $85,574 were payable as of December 31, 2018 and 2017, respectively, for the amount by which 6% of revenue exceeded the applicable fixed fee. As of January 1, 2019, the Company, again, is obligated to pay the greater of $400,000 or 6% of annual revenues until the obligation is paid in full. As of that date and continuing until the remaining obligation has been paid in full, interest on the remaining unpaid obligation will accrue and compound annually at a rate of 2.5% per year. Accrued interest on this unpaid obligation is payable on the date that the remaining obligation is paid in full. The obligation was, but is no longer, secured by certain patents and trademarks.

Minimum payments to be made in 2019 include $363,686 of revenue-based payments payable as of December 31, 2018 and an estimate of additional revenue-based payments to be made throughout the remainder of 2019 relating to revenue generated in the first, second and third quarters of 2019 using actual revenue generated in the same quarters in 2018. Minimum payments for the remaining years include only the minimum payments for each year. Actual payments could be significantly more than provided in the table, to the extent that 6% of the Company's annual revenue in 2020 and beyond exceeds $400,000:

2019	$ 1,290,234
2020	400,000
2021	400,000
2022	400,000
2023	400,000
2024 and beyond	3,996,387
Total NuvoGen obligation payments	6,886,621
Plus interest accretion	106,132
Total NuvoGen obligation, net	$ 6,992,753

The Company has 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. The unamortized debt discount was $(106,132) and $(118,612) at December 31, 2018 and 2017, respectively. Discount accreted during the years ended December 31, 2018 and 2017 was $(12,480), and $195,248, respectively.

Illumina, Inc. Agreement

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

Under the Restated Agreement, the parties have agreed to continue activities under the first development plan which was entered into pursuant to the Original Agreement, and the Company may, at its discretion, submit additional development plans for IVD test kits in the Field to Illumina for its approval, not to be unreasonably withheld.

Under each development plan, Illumina will provide specified regulatory support and rights, and develop and deliver to the Company an executable version of custom software, which, when deployed on Illumina's MiSeqDx sequencer, would enable sequencing by the end-user of the subject IVD test kit probe library. Illumina retains ownership of the custom software, subject to the Company's right to use the custom software in connection with the commercialization of IVD test kits. The Company is required to pay Illumina up to $0.6 million in the aggregate upon achievement of specified regulatory milestones relating to the IVD test kits, though none of these regulatory milestones have been reached through December 31, 2018. In addition, the Company has agreed to pay Illumina a single digit percentage royalty on net sales of any IVD test kits that the Company commercializes pursuant to the Restated Agreement.

As a result of IVD test kit development plans submitted by the Company to Illumina in accordance with the Restated Agreement, the Company paid Illumina $12,500 and $50,000 for the years ended December 31, 2018 and 2017, respectively. Costs incurred for development plans under the Restated Agreement have been expensed as incurred to research and development expense in the accompanying consolidated statements of operations.

Absent earlier termination, the Restated Agreement will expire in May 2027; however, Illumina is no longer obligated to notify the Company of changes in its products that may affect the Company's IVD test kits after May 31, 2023. The Company may terminate the Restated Agreement at any time upon 90 days' written notice and may terminate any development plan under the Restated Agreement upon 30 days' prior written notice. Illumina may terminate the Restated Agreement upon 30 days' prior written notice if the Company undergoes certain changes of control, subject to a transition period of up to 12 months for then-ongoing development plans. Either party may terminate the Restated Agreement upon the other party's material breach of the Restated Agreement that remains uncured for 30 days, or upon the other party's bankruptcy.

Other Agreements with Related Parties

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

Note 11. Net Loss Per Share

Basic loss per common 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. Diluted loss per common share is computed similar to basic loss per share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table provides 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,	
	2018	2017
Numerator:		
Net loss	$(16,453,918)	$(18,960,017)
Denominator:		
Weighted-average shares outstanding-basic and diluted	27,523,463	10,597,318
Net loss per share, basic and diluted	$ (0.60)	$ (1.79)

The following outstanding options, warrants, restricted stock units and debt conversion option 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,	
	2018	2017
Options to purchase common stock	2,047,237	1,517,771
Common stock warrants	237,846	219,723
Restricted stock units	227,707	26,666
QNAH convertible note	777,769	755,178

Note 12. Warrants

In connection with certain of its redeemable convertible preferred stock issuances, convertible debt financings and other financing arrangements, the Company has issued warrants for shares of its common stock and various issues of its redeemable convertible preferred stock which have since been converted to common stock warrants.

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 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 entry into convertible note agreements, the Company agreed to issue warrants ("Convertible Note Warrants") to the holders 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.

The following table shows the common stock warrants outstanding as of December 31, 2018:

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

Note 13. Stockholders' Deficit

Public Offerings

ATM Offering

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

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

Underwritten Public Offering

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

Common Stock

Pursuant to the Company Amended and Restated Certificate of Incorporation, the Company is authorized to issue 200,000,000 shares of common stock at a par value of $0.001 per share. As of December 31, 2018, 28,585,449 shares were issued and outstanding. As of December 31, 2017, 13,929,763 shares were issued and outstanding.

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' deficit on the consolidated 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. 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. There was no additional treasury stock activity for the years ended December 31, 2018 and 2017.

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 under its equity incentive plans of RSUs and stock options to employees, non-employee directors and consultants of the Company and its affiliates and through its employee stock purchase plan. Amounts recognized in the accompanying consolidated statements of operations with respect to the Company's stock-based compensation and employee stock purchase plan were as follows:

	Years Ended December 31,	
	2018	2017
Selling, general and administrative	$ 1,709,945	$ 1,012,253
Research and development	172,005	319,916
Cost of product and product-related services revenue	65,064	103,918
	$ 1,947,014	$ 1,436,087

Equity Incentive Plans

The Company initially established the 2001 Stock Option Plan (the "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 (the "2011 Plan").

In February 2014, 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 (the "2014 Plan"), including 14,006 remaining shares reserved under the 2011 Plan. As of December 31, 2018, there were no shares available for issuance under the 2014 Plan. On January 1, 2019, an additional 1,143,417 shares were registered for issuance under the 2014 Plan pursuant to an evergreen provision contained in the 2014 Plan.

The Company's Board of Directors determines the grant date for all awards granted under the 2014 Plan. The option exercise price of stock options granted is generally equal to the closing price of the Company's common stock on the date of grant. All stock options granted have a ten-year term. The vesting period of stock options and RSUs is established by the Board of Directors but typically ranges between one and four years.

The following table summarizes stock option activity during the two-year period ended December 31, 2018:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at January 1, 2017	1,161,705	$ 3.35	7.7	$ 36,887
Granted	494,500	2.09		
Exercised	(41,815)	2.68		$ 152,130
Forfeited	(81,676)	2.64		
Expired/Cancelled	(14,943)	6.15		
Balance at December 31, 2017	1,517,771	$ 2.97	7.5	$ 67,242
Granted	802,500	3.39		
Exercised	(144,645)	2.19		$ 243,531
Forfeited	(66,428)	3.24		
Expired/Cancelled	(61,961)	6.52		
Balance at December 31, 2018	2,047,237	$ 3.07	7.6	$ 366,007
Vested and expected to vest at December 31, 2018	2,047,237	$ 3.07	7.6	$ 366,007
Exercisable at December 31, 2017	851,996	$ 3.31	6.5	$ 248
Exercisable at December 31, 2018	1,256,352	$ 2.91	6.5	$ 346,595

The weighted-average fair value of stock options granted was $2.29 and $1.14 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, total unrecognized compensation cost related to stock option awards was approximately $1,675,285, which is expected to be recognized over approximately 3.04 years.

In June 2018, in connection with the retirement of two employees, the vesting of stock options covering 46,613 shares of common stock was accelerated and the post-termination exercise period for the employees' options was extended to a one-year period from the termination date. As a result of this modification, the Company recorded incremental stock-based compensation expense of approximately $79,400 for the year ended December 31, 2018.

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 stock options granted for the periods presented were as follows:

	2018	2017
Fair value of common stock	$3.26 - 5.06	$1.71 - 3.46
Risk-free interest rate	2.59% - 2.82%	1.75% - 2.20%
Expected volatility	79.5% - 85.8%	58.5% - 62.6%
Expected term	5.3 to 5.5 years	5.1 to 6.3 years
Expected dividend yield	0%	0%

- *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 stock 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 preparing its Black-Scholes option-pricing model fair value calculations, in accordance with ASU No. 2016-09, the Company does not estimate a forfeiture rate to calculate stock-based compensation. The Company uses judgment in evaluating the expected volatility and expected terms 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, 2018:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at January 1, 2017	355,499	$ 2.41
Granted	10,000	1.75
Vested	(336,333)	2.47
Forfeited	(2,500)	2.46
Balance at December 31, 2017	26,666	$ 2.78
Granted	492,051	3.63
Released	(291,010)	3.72
Balance at December 31, 2018	227,707	$ 3.30
Vested and unissued at December 31, 2018	13,126	$ 3.40

The weighted-average fair value of RSUs granted was $3.63 and $1.75 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, total unrecognized compensation cost related to RSU awards was approximately $701,780, which is expected to be recognized over approximately 3.30 years.

Vested and unissued awards at December 31, 2018 represents RSU awards granted on August 16, 2018 for which the second vesting date was December 31, 2018, but for which issuance of awards occurred on the next business day, January 2, 2019.

2014 Employee Stock Purchase Plan

In April 2015, the Company's stockholders approved the 2014 Employee Stock Purchase Plan ("ESPP"), which became effective in May 2015. Initially, the ESPP authorized the issuance of up to 110,820 shares of common stock pursuant to 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, 2018, employees purchased 39,993 shares at $1.57 per share, 35,805 shares at $1.57, and 4,176 shares at $2.81 per share at the end of each of the ESPP's six-month purchase periods. During the year ended December 31, 2017, employees purchased 39,972 shares at $1.79 per share and 39,969 shares at $1.61 per share at the end of each of the ESPP's six-month purchase periods. As of December 31, 2018, approximately 158,067 shares of the Company's common stock were reserved for future issuance under the ESPP. On January 1, 2019, an additional 195,000 shares were registered for issuance pursuant to an evergreen provision contained in the ESPP.

The Company recognizes ESPP expense based on the fair value of the ESPP stock purchase rights, estimated for each six-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.

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:

	2018	2017
Fair value of common stock	$1.85 - 4.00	$2.11 - 3.17
Risk-free interest rate	1.88% - 2.07%	0.61% - 1.12%
Expected volatility	83.2% - 85.8%	68.0% - 70.0%
Expected term	0.5 years	0.5 years
Expected dividend yield	0%	0%

- *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.

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. Cash received from the sale of common stock by the Company to eligible participants for the year ended December 31, 2018 was $9,997 which resulted in the sale of 2,304 shares of the Company's common stock at fair market value. Cash received from the sale of common stock by the Company to eligible participants for the year ended December 31, 2017 was $130,649 which resulted in the sale of 61,141 shares of the Company's common stock at fair market value.

Note 14. Commitments and Contingencies

Compensation Agreements

In September 2017, the Company entered into an arrangement with certain of its non-executive officer employees to provide for retention bonus payments to those eligible employees providing continuing service to the Company through July 31, 2018 and December 31, 2018, with one half of the retention bonus commitment payable at each of these dates. For the years ended December 31, 2018 and 2017, compensation expense of $881,336 and $358,744 has been included in the accompanying consolidated statements of operations. No forfeiture rate was estimated for this accrued liability. Instead, forfeitures were recognized as they occurred during the period. $635,377 and $358,744 of accrued retention bonus was included in accrued liabilities in the accompanying consolidated balance sheets as of December 31, 2018 and 2017, respectively. The remaining payment was made to eligible employees in January 2019.

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 and the lessor, respectively, which improvements expanded and improved the Company's existing research, development, operations and administrative 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 consolidated balance sheets, and is being accreted at $11,833 per month over the lease term as a reduction of rent expense.

In December 2018, HTG France signed a commercial lease for office and laboratory space in Sausheim, France effective January 1, 2019. The term of the lease is nine years, extending through December 31, 2028. However, HTG France maintains the right under this agreement to terminate the lease once every three years, subject to a prior notice period to the landlord of six months. Annual fixed lease payments under this agreement are 8,200 Euro plus service charges of 1,200 Euro, to be paid to the landlord on a monthly basis.

The Company's annual minimum lease payments relating to its Tucson and Sausheim facilities leases before common area maintenance charges are as follows as of December 31, 2018:

2019	$ 525,745
2020	528,225
2021	53,907
2022	10,768
2023	10,768
2024 and beyond	43,073
	$ 1,172,486

Rent expense, including common area maintenance costs for the Company's facilities leases was $583,182, including $142,000 of depreciation for capitalized leasehold improvements for the year ended December 31, 2018. Rent expense, including common area maintenance costs for the Company's facility leases was $570,979, including $142,000 of depreciation for capitalized leasehold improvements for the year ended December 31, 2017.

As of December 31, 2018, the Company also has capital lease commitments consisting of approximately $92,445 under leases for computer equipment varying in length from 36-48 months 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 consolidated balance sheets for the years ended December 31, 2018 and 2017:

	Years Ended December 31.	
	2018	2017
Beginning balance	$ 37,156	$ 50,426
Cost of warranty claims	(2,596)	(9,814)
Increase in warranty reserve	28,901	(3,456)
Ending balance	$ 63,461	$ 37,156

Defined Contribution Plan

In January 2003, the Company established a defined contribution plan ("401(k) Plan") under section 401(k) of the IRC. All employees who are over the age of 21 and who are expected to work at least 1,000 hours in a calendar year are eligible for participation in the 401(k) Plan upon commencement of employment with the Company. The Company may make discretionary contributions to the 401(k) Plan, but has not done so during the years ended December 31, 2018 and 2017.

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 accompanying consolidated 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. As discussed below, the Company has estimated $1,538,220 and $0 of uncertain tax positions as of December 31, 2018 and 2017, respectively.

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, 2018 or 2017, and has not recognized interest or penalties during the years ended December 31, 2018 and 2017, since there was no reduction in income taxes paid due to uncertain tax positions. Management of the Company does not expect a material change to the amount of unrecognized tax benefits to occur within the next 12 months.

The components of income tax expense are as follows:

	Years Ended December 31,	
	2018	2017
Current:		
Federal	$ —	$ —
State	3,526	2,921
Total current income tax expense	$ 3,526	$ 2,921
Deferred:		
Federal	$ —	$ —
State	—	—
Total deferred income tax expense	$ —	$ —
Total income tax expense	$ 3,526	$ 2,921

The Company's actual income tax expense for the years ended December 31, 2018 and 2017 differ from the expected amount computed by applying the statutory federal income tax rate to loss before income taxes as follows:

	Years Ended December 31,	
	2018	2017
Computed tax (benefit) at statutory rate (2018: 21%, 2017: 34%)	$ (3,454,582)	$ (6,445,413)
State taxes, net of federal benefit	(384,035)	(532,952)
Stock-based compensation	82,024	231,396
Foreign tax rate differential	(3,158)	—
Return to provision	(31,111)	(15,375)
Other	51,598	20,292
Research and development tax credit - state	(511,845)	(576,525)
Research and development tax credit - federal	(506,364)	(440,058)
Federal rate change on deferred items as of enactment date	—	16,232,211
Uncertain tax position adjustment for prior periods	1,029,115	—
Increase (decrease) in valuation allowance	3,731,884	(8,470,655)
	$ 3,526	$ 2,921

Deferred tax assets and liabilities comprise the following:

	Years Ended December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 33,431,082	$ 29,475,597
Research and development credits	3,076,441	3,114,091
Deferred revenue	86,567	204,061
Inventory reserve	9,645	15,134
Fixed assets and intangibles	223,767	147,395
Accrued NuvoGen liability	1,720,335	1,952,567
Accrued expense	86,034	24,500
Other	106,913	74,986
	38,740,784	35,008,331
Valuation allowance	(38,740,784)	(35,008,331)
Deferred tax asset, net	$ —	$ —

On December 22, 2017, the U.S. government enacted the Tax Act, which makes broad and complex changes to the IRC. Certain of these changes are applicable to the Company in 2018 and thereafter, including but not limited to, reducing the U.S. federal corporate tax rate from 35% to 21%, creating a new limitation on deductible interest expense, eliminating the corporate alternative minimum tax, modifying the rules related to uses and limitations of net operating loss carryforwards generated in tax years ending after December 31, 2017, enhancing bonus depreciation, and changing the rules pertaining to the taxation of profits earned abroad. Changes in tax rates and tax laws are accounted for in the period of enactment. The Tax Act reduced the corporate tax rate to 21% effective January 1, 2018. Consequently, the Company recorded a decrease related to deferred tax assets of $16,232,211, exclusive of the corresponding change in the valuation allowance, as of December 31, 2017. Due to the full valuation allowance on the deferred tax assets, there was no net adjustment to deferred tax expense or benefit for the year ended December 31, 2017, resulting from the reduction of the corporate tax rate.

As of December 31, 2018, the Company has estimated federal and state net operating loss (“NOL”) carryforwards of approximately $138,759,835 and $89,208,791 for federal and state income tax purposes, respectively. The Company’s federal NOLs are scheduled to expire from 2021 through 2038. The Company’s state NOLs are scheduled to expire from 2027 through 2038. The Company has an estimated French NOL carryforward of $38,618 as of December 31, 2018, with no expiration date. The Company’s federal and state tax credit carryforwards begin expiring in 2021 and 2019, respectively. The Company’s federal NOL carryforwards have the following expiration dates:

	Year of Expiration	Carryforwards
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	21,112,183
	2036	24,302,042
	2037	18,986,265
	2038	16,983,240
		$138,759,835

For financial reporting purposes, valuation allowances of $38,740,784 and $35,008,331 at December 31, 2018 and 2017, respectively, have been established to offset deferred tax assets relating primarily to NOLs and research and development credits. The increase in the valuation allowance of $3,732,453 for the year ended December 31, 2018 was primarily due to increased operating losses. The Company has established a valuation allowance against its entire tax asset. As a result, the Company does not recognize any tax benefit until it is in a taxpaying position or there is sufficient positive evidence leading to the conclusion that it is 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 IRC. Provisions of the IRC place special limitations on the usage of NOLs 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.

A reconciliation of the Company's gross unrecognized tax benefits is as follows:

	Years Ended December 31,	
	2018	2017
Balance at beginning of year	$ —	$ —
Increases to prior positions	1,029,115	
Increases for current year positions	509,105	—
Balance at end of year	$ 1,538,220	$ —

As of December 31, 2018, the Company had $1,538,220 of gross unrecognized tax benefits, related to research and experimental tax credits. The Company had no unrecognized tax benefits as of December 31, 2018, which, if recognized, would affect the annual effective tax rate, due to the full valuation allowance on the deferred tax assets.

The Company files income tax returns in the United States, Arizona, California, Texas, various other state jurisdictions, and France, with varying statutes of limitations. As of December 31, 2018, the earliest year subject to examination is 2015 for U.S. federal tax purposes. The earliest year subject to examination is 2014 for Arizona, California and Texas, 2009 for the remaining state jurisdictions, and 2018 for France. However, the Company's NOL 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

QML Master Assay Development, Commercialization and Manufacturing Agreement

In November 2016, the Company and QML entered into the Governing Agreement, which creates a framework for QML and the Company to combine their technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays. Under the Governing Agreement, the parties jointly seek companion diagnostic programs with biopharmaceutical companies, QML enters into sponsor project agreements with interested biopharmaceutical companies for specified projects, and QML and the Company enter into statements of work, which set 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 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 provides additional financial terms for the corresponding Project, which terms depend on the respective development and/or commercialization activities of the parties.

The Governing Agreement has a five-year term. However, either party may terminate the Governing 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, except neither party will have such change of control termination right to the extent the termination of the Governing Agreement relates to SOW One, SOW Two or SOW Three (each defined below). 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.

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

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

Statement of Work No. One

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

Revenue of $2,297,742, including only SOW One Monthly Fees, and $99,394 of SOW One profit sharing payments has been included in collaborative development services revenue in the accompanying consolidated statements of operations for the year ended December 31, 2018, compared to $2,604,892 , including only SOW One Monthly Fees and $1,272,080 of SOW One profit sharing payments, for the year ended December 31, 2017. Costs relating to development activities conducted by the Company pursuant to SOW One of $1,716,115 and $2,129,138 have been included in research and development expense in the accompanying consolidated statements of operations for the years ended December 31, 2018 and 2017, respectively. Accounts receivable relating to SOW One of $0 and $2,429,152 remained in the accompanying consolidated balance sheets as of December 31, 2018 and 2017, respectively.

Statement of Work No. Two

In October 2017, the Company and QML entered into the second statement of work under the Governing Agreement ("SOW Two"), which was made effective as of June 2, 2017 ("Onset Date"). The Company and QML amended SOW Two twice in August 2018 and an additional time in September 2018.

SOW Two addresses development activities conducted by the Company and QML since the Onset Date and those expected to be further conducted by parties in connection with what is expected to be a multi-stage project leading to the potential development and commercialization of an NGS-based companion diagnostic assay in support of one or more therapeutic product candidate development and commercialization programs for a third-party pharmaceutical company. The initial-phase investigational use only ("IUO") development activities under SOW Two have been completed and the first two amendments of SOW Two relate to the next phases, which include the use of the IUO assay developed in the initial-phase in a retrospective clinical trial and in additional disease indications. The third amendment to SOW Two provides that profit sharing relating to the original development activities and the development activities contemplated by the first SOW Two amendment will, in each case, commence upon the later of (i) the third amendment effective date, which is September 27, 2018, and (ii) the completion of the respective development activities, rather than at the end of each calendar quarter, provided that such modification to the profit-sharing commencement date only applies to development activities that had not yet been subject to profit-sharing as of the third amendment effective date. QML will continue to pay the Company for the development services to be performed under SOW Two. The Company and QML will share in any net profits (as determined under the Governing Agreement) generated during the work on an approximately quarterly basis throughout the term of SOW Two, except as otherwise specified in the third amendment to SOW Two.

The Supplement Agreement initially entered into concurrent with SOW Two was also amended in August 2018 and made effective as of July 2018. This amendment establishes certain rights and obligations of the parties with regard to confidential information and other intellectual property needed to perform, and/or produced as a result of the next phase project activities contemplated by the SOW Two amendments and does not materially change the terms and conditions agreed upon by the parties in the original Supplement Agreement.

Revenue of $5,988,021, including SOW Two Monthly Fees of $4,208,194 and SOW Two profit sharing payments of $1,779,827, has been included in collaborative development services revenue in the accompanying consolidated statements of operations for the year ended December 31, 2018. Revenue of $4,060,341, including SOW Two Monthly Fees of $2,988,211 and SOW Two profit sharing payments of $1,072,130 has been included in collaborative development services revenue in the accompanying consolidated statements of operations for the year ended December 31, 2017. Costs relating to development activities conducted by the Company pursuant to SOW Two of $3,625,332 and $2,645,825 have been included in research and development expense in the accompanying consolidated statements of operations for the years ended December 31, 2018 and 2017, respectively. Accounts receivable relating to SOW Two of $1,007,950 and $1,796,157 remained in the accompanying consolidated balance sheets as of December 31, 2018 and 2017, respectively.

Statement of Work No. Three

In January 2018, the Company and QML entered into a third statement of work under the Governing Agreement ("SOW Three") and amended SOW Three in September 2018. SOW Three relates to development activities for a next generation sequencing-based clinical-trial assay ("SOW Three Project") in connection with a sponsor project agreement between QML and a pharmaceutical company ("Pharma Three"). Initial assay development activities under SOW Three have been completed, and the first amendment to SOW Three provides for the development of an IUO assay, subsequent retrospective testing of clinical trial samples, design verification and, subject to satisfactory achievement of relevant performance and regulatory milestones, regulatory submissions in the United States and EU necessary for the commercialization of a companion diagnostic for a corresponding Pharma Three drug.

Under the terms of SOW Three, the Company has agreed to assign its rights in certain SOW Three Project-related intellectual property ("Project IP") predominantly related to Pharma Three's drug candidate(s) to QML for ultimate assignment to Pharma Three in accordance with the sponsor project agreement between QML and Pharma Three. Improvements to the background intellectual property of the Company, QML and Pharma Three generally will be owned solely by the respective party. Otherwise, Project IP will be jointly owned among the Company, QML and Pharma Three.The development activities to be performed under SOW Three are expected to extend through the first half of the fiscal year ended December 31, 2020, with key development milestones, testing and regulatory filings occurring throughout the period. QML will pay the Company for the development services performed for SOW Three. In addition, the Company and QML will share in any net profits (as determined under the Governing Agreement) generated during the work on an approximately quarterly basis throughout the term of SOW Three.

Revenue of $3,997,346, including SOW Three Monthly Fees of $3,641,715 and SOW Three profit sharing payments of $355,631 have been included in collaborative development services revenue in the accompanying consolidated statements of operations for the year ended December 31, 2018. Costs relating to development activities conducted by the Company pursuant to SOW Three of $2,667,030 have been included in research and development expense in the accompanying consolidated statements of operations for the year ended December 31, 2018. No costs or revenue relating to SOW Three were included in the accompanying consolidated statements of operations for the year ended December 31, 2017 as SOW Three was not established until January 2018. Accounts receivable relating to SOW Three of $363,869 and $0 remained in the accompanying consolidated balance sheets as of December 31, 2018 and 2017, respectively.

QNAH Stock Purchase Agreement

Pursuant to a stock purchase agreement, entered concurrent with the Governing Agreement, QNAH, 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.

The purchase price for the shares of common stock purchased by QNAH 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. The Company recognized $35,000 and $4,375 of this consideration as revenue for the years ended December 31, 2018 and 2017, respectively.

The second tranche closing contemplated by the stock purchase agreement did not occur, and accordingly, QNAH did not purchase any additional shares under the stock purchase agreement. QNAH does not have, and as of December 31, 2017 did not have, any further obligation to purchase common stock under the stock purchase agreement.

QNAH Convertible Note Agreement

In October 2017, the Company issued a subordinated convertible promissory note to QNAH in the principal amount of $3.0 million against receipt of cash proceeds equal to such principal amount. The QNAH Convertible Note bears simple interest at the rate of 3.0% per annum and matures on October 26, 2020 (the "Maturity Date"). Neither interest nor principal payment are due until the Maturity Date, subject to earlier conversion. QNAH may elect to convert all or any portion of the outstanding principal balance of the Note and all unpaid accrued interest thereon at any time prior to the Maturity Date into shares of the Company's common stock at a conversion price of $3.984 per share.

Debt issuance costs of $25,787 and $40,510 relating to the QNAH Convertible Note are being presented as a direct reduction of Convertible Note, related party – net of debt issuance costs as of December 31, 2018 and December 31, 2017, respectively. Amortization of the QNAH Convertible Note deferred financing costs was $13,454 and $1,269 for the years ended December 31, 2018 and 2017, respectively. Interest accrued on the QNAH Convertible Note for the years ended December 31, 2018 and 2017 was $90,000 and $8,630, respectively. Both amounts were included in interest expense in the accompanying consolidated statements of operations.

Note 17. Subsequent Events

On February 15, 2019, the Company and QML entered into a fourth amendment of SOW Two (see Note 16), effective as of February 5, 2019 (such amendment, the "Fourth SOW Two Amendment"). The Fourth SOW Two Amendment contemplates the use of the IUO assay developed in the previous phases of SOW Two in multiple biopharmaceutical company partner clinical trials and additional development activities which potentially could be included in a future companion diagnostic regulatory submission.

The development activities to be performed under the Fourth SOW Two Amendment are expected to be completed by the end of 2019. QML has agreed to pay the Company development fees in the low, single-digit millions of dollars for the additional assay development activities. In addition, the Company and QML will share in any net profits (as determined under the Governing Agreement) generated by this development work.

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

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	57	Chief Executive Officer and Director[(a)]
John L. Lubniewski	55	President and Chief Operating Officer[(b)]
Shaun D. McMeans	57	Senior Vice President and Chief Financial Officer
Non-Employee Directors		
Ann F. Hanham, Ph.D. (3)	66	Chair of the Board of Directors[(c)]
Harry A. George (1)	70	Director
Donnie B. Hardison (2)	68	Director
James T. LaFrance (1)(2)(3)	60	Director
Lee R. McCracken (2)(3)	61	Director
Michelle R. Griffin (1)	53	Director

(a) In January 2019, our board of directors designated Mr. Johnson as the Executive Chairman of our board of directors, effective March 31, 2019. Concurrently with Mr. Johnson's appointment as our Executive Chairman, Mr. Johnson will discontinue serving as our Chief Executive Officer.

(b) In January 2019, our board of directors appointed Mr. Lubniewski as our Chief Executive Officer, effective March 31, 2019. At such time, Mr. Lubniewski will continue to serve as our President but will no longer have the separate title and role of Chief Operating Officer.

(c) In January 2019, our board of directors designated Dr. Hanham as our Lead Independent Director, effective March 31, 2019, a position in which she will serve in lieu of her current position as Chair of our board of directors.

(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 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. ("Ventana"), a medical diagnostics company, prior to its acquisition by Roche Holdings, Inc. ("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 Chief Executive Officer qualify him to serve on our board of directors.

John L. Lubniewski. Mr. Lubniewski has served as our President and Chief Operating 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 ("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.

Shaun D. McMeans. Mr. McMeans has served as our Senior Vice President 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.

Non-Employee Directors

Ann F. Hanham Ph.D. Dr. Hanham has served on our board of directors since August 2016, and, since March 2017, as the chair of our board of directors. 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. ("Otsuka"), Celtrix Pharmaceuticals, Inc. ("Celtrix"), and Becton Dickinson and Company ("BD"). InterMune, Inc., 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 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 Dr. 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 serves as President and CFO of Radiance Therapeutics where he also serves on the board of directors. 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 Medipacs, Inc., Post.Bid.Ship, Inc., AdiCyte, Inc. and RxActuator, Inc. and Splash Pharmaceuticals, Inc. Mr. George is also a member of the boards of directors of several non-profit organizations, including Southern Arizona Leadership Council, Desert Angels and Start-up Tucson, a member of the Board of Visitors of the McGuire Center for Entrepreneurship, and an advisor to Tech Launch Arizona. 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. He currently is the President and Chief Executive Officer, and serves on the board of directors, of Biotheranostics, Inc., a molecular-based diagnostic company, positions he has held since February 2017. From April 2016 to January 2017, Mr. Hardison served as the sole proprietor of DMH Consulting, a management consulting firm, which he founded. Between April 2010 and March 2016, Mr. Hardison was the President and Chief Executive Officer of Good Start Genetics, a medical testing 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 ("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 as an independent director on the boards of directors of several private companies, including Seventh Sense Biosystems, Boston Microfluidics and IQuity, Inc. 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), 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. Mr. LaFrance also serves on the boards of directors of a number of private companies, including BioArray Genetics and Personal Genome 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 R. McCracken. Mr. McCracken has served on our board of directors since October 2015. Mr. McCracken currently is the Chief Executive Officer and a member of the board of directors of Drawbridge Health, Inc., a company focused on enabling personal diagnostic testing, positions he has held since June 2017. From May 2016 to May 2017 and from April 2013 to March 2014, he served as a strategic and restructuring consultant in the regenerative medicine and diagnostic sectors for McCracken Consulting, a consulting firm he founded. Between April 2014 and May 2016, Mr. McCracken was Chief Executive Officer of Gensignia Life Sciences, Inc., a molecular 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 Pathwork Diagnostics, Inc., Prometheus Laboratories Inc., 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. 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.

Michelle R. Griffin. Ms. Griffin has served on our board of directors since August 2018. Ms. Griffin provides consulting services to biotechnology companies and boards of directors through her firm, Pacific Biotechnology Consulting Group. Ms. Griffin currently serves as a member of the board of directors and chair of the audit committee for Acer Therapeutics, Inc (Nasdaq: ACER). She has also served on the board of directors and as audit committee chair for PhaseRx, Inc. (Nasdaq:PZRX) from 2016 to 2018, OncoGenex Pharmaceuticals Inc. (Nasdaq: OGXI) from 2008 to 2011, and Sonus Pharmaceuticals, Inc. (Nasdaq: SNUS) from 2004 to 2008; as chair of the board of directors for Universal Cells, Inc. from 2017 until its acquisition by Astellas Pharma Inc. in 2018; as a member of the board of directors of Virginia Mason Health System and Virginia Mason Medical Center from 2014 to 2018; and as a member of the board of directors for Polynoma LLC from 2012 to 2014. Ms. Griffin served as Executive Vice President, Operations, and Chief Financial Officer at OncoGenex from 2011 to 2013; served as acting Chief Executive, Senior Vice President and Chief Operating Officer at Trubion Pharmaceuticals, Inc. from 2009 until its acquisition in 2010 and as Chief Financial Officer from 2006 to 2009; and served as Senior Vice President and Chief Financial Officer of Dendreon Corp. from 2005 to 2006. Ms. Griffin began her career in the biopharmaceuticals industry in 1994 at Corixa Corp. and served as Chief Financial Officer from its IPO in 1997 until 2005 when Corixa was acquired by GlaxoSmithKline plc. She received a post-graduate certificate in accounting and an MBA from Seattle University, a B.S. in statistics and marketing from George Mason University and has passed the certified public accountant exam. Our board of directors believes that Ms. Griffin's financial and accounting expertise and extensive executive experience qualifies her 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 seven members as of December 31, 2017. 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 2020; and
- Class III, which consists of Mr. Johnson, Dr. Hanham and Ms. Griffin, whose terms will expire at our annual meeting of stockholders to be held in 2021.

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 presently serves as the Chief Executive Officer while Dr. Hanham serves as the chair of our board of directors but is not an officer.

Commencing March 31, 2019, Mr. Lubniewski will serve as our Chief Executive Officer, Mr. Johnson will discontinue serving in such capacity and Mr. Johnson will serve as our Executive Chairman. As our Executive Chairman, Mr. Johnson will advise our management, including our Chief Executive Officer, on various strategic matters. We believe that separation of the positions of Executive Chairman and Chief Executive Officer will reinforce the independence of the board of directors in its oversight of our business and affairs. In addition, we have a separate chair for each committee of our board of directors. The chair of each committee is expected to report at least annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

In addition, our board of directors has designated Dr. Hanham to serve as our Lead Independent Director, effective March 31, 2019. As Lead Independent Director, Dr. Hanham will, among other things, preside over board of directors meetings, set meeting agendas, ensure the duties, responsibilities and roles of members of our board of directors are clearly understood, ensure that our board of directors receives appropriate and timely information, material and reports from management regarding our business, provide input to the board of directors regarding candidates for nomination or appointment to the board and board committees, and perform such additional duties as set forth in our bylaws and as our board of directors may otherwise determine and delegate.

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 Ms. Griffin, Mr. George and Mr. LaFrance. Ms. Griffin 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 consolidated 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 Ms. Griffin 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 Ms. Griffin'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. Hardison, Mr. McCracken, and Mr. LaFrance. Mr. Hardison 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 (the "Exchange Act") 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.

In 2018, our compensation committee retained Radford, an Aon Hewitt company and a provider of compensation market intelligence to the technology and life sciences industries, to provide a report summarizing relevant benchmark data relating to industry-appropriate peers and make recommendations regarding base salary, target total cash (base salary plus target cash incentives) and the amounts and terms of long-term equity incentive awards for our executives as well as to benchmark and make recommendations regarding the initial and annual cash retainer amounts for directors and chairpersons of our board of directors and the various committees and the amounts and terms of initial and annual long-term equity incentive awards for directors. No work performed by Radford during fiscal year 2018 raised a conflict of interest.

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

Our nominating and governance committee consists of Dr. Hanham, Mr. McCracken and Mr. LaFrance. Dr. Hanham serves as the chair of our nominating and governance 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, 2018.

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, 2018, which consist of our principal executive officer and our two other most highly compensated executive officers as of December 31, 2018, are as follows:

- Timothy B. Johnson, our Chief Executive Officer;
- John L. Lubniewski, our President and Chief Operating Officer; and
- Shaun D. McMeans, Senior Vice President Finance and Chief Financial Officer.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Bonus ($) (1)	Stock awards ($) (2)	Option awards ($) (3)	Non-equity incentive plan compensation ($) (4)	All other compensation ($) (5)	Total ($)
Timothy B. Johnson	2018	426,250	200,000	708,343	510,000	166,183	741	2,011,517
Chief Executive Officer	2017	409,500	167,500	117,600	36,480	267,800	38,408	1,037,288
John L. Lubniewski	2018	327,230	100,000	413,775	340,000	116,007	741	1,297,753
President and Chief Operating Officer	2017	306,792	105,739	58,800	38,400	160,346	20,492	690,569
Shaun D. McMeans	2018	288,608	50,000	270,437	340,000	91,438	741	1,041,224
Senior Vice President and Chief Financial Officer	2017	255,738	80,110	50,600	35,520	134,316	18,786	575,070

(1) The dollar amounts in this column represent the following bonus payments: For Mr. Johnson, $200,000 paid in 2018 in recognition of certain financing transactions in 2018, $142,500 paid in 2017 in recognition of 2016 corporate performance and our achievement of the financing goal described in note (4) below and $25,000 paid in 2017 in recognition of certain commercial and other financing transactions in 2016; for Mr. Lubniewski, $100,000 paid in 2018 in recognition of certain financing transactions in 2018, $85,739 paid in 2017 in recognition of 2016 corporate performance and our achievement of the financing goal described in note (4) below and $20,000 paid in 2017 in recognition of certain commercial and other financing transactions in 2016; and for Mr. McMeans, $50,000 paid in 2018 in recognition of certain financing transactions in 2018, $70,110 paid in 2017 in recognition of 2016 corporate performance and our achievement of the financing goal described in note (4) below, and $10,000 paid in 2017 in recognition of certain commercial and other financing transactions in 2016.

(2) The dollar amounts in this column represent the aggregate grant date fair value of RSU awards granted in 2018 and 2017, as applicable. For further discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(3) The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2018 and 2017, as applicable. These amounts have been computed in accordance with FASB ASC Topic 718, using the Black-Scholes option pricing model. For a discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(4) Amounts shown represent annual performance-based bonuses earned for 2018 and 2017. In April 2017, our board of directors made the receipt of the annual performance-based bonuses for 2016 expressly conditioned upon the completion by us of a financing transaction or series of related financing transactions in which we raised aggregate gross proceeds in excess of $12.0 million and, with respect to each named executive officer, his continued employment through completion of such financing transaction(s). Because payment of the performance-based bonuses for 2016 was made expressly conditioned on the achievement of the foregoing financing goal (which was achieved in May 2017), the non-equity incentive plan compensation reportable for 2016 for each named executive officer was $0, and the performance-based bonuses paid with respect to 2016 are reflected as a bonus for 2017 as described in note (1) above.

(5) Amount shown represents premiums for life, disability and accidental death and dismemberment insurance paid by us on behalf of the named executive officer and reimbursement to the named executive officers of the employee portion of taxes paid at the vesting of the RSU awards granted on August 26, 2016 which vested in February and August of 2017.

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 by our board of directors, based on the recommendation of the compensation committee of our board of directors and following analyses conducted by independent third-party consultants. At the beginning of 2018, the base salaries for our named executive officers were $412,000, $308,358 and $258,300, for Mr. Johnson, Mr. Lubniewski and Mr. McMeans, respectively. In February 2018, the base salary for Mr. McMeans was increased to $275,000. In connection with Mr. Lubniewski's promotion to President and Chief Operating Officer in April 2018, Mr. Lubniewski's base salary was increased to $335,000. In August 2018, the base salaries for Mr. Johnson and Mr. McMeans were increased to $450,000 and $315,000, 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. As with annual base salary, the target annual performance-based bonus percentage for each of our named executive officers is determined based upon input from independent third-party consultants. The annual performance-based bonus each named executive officer is awarded 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 2018, 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 through August 15, 2018 and 55% of his base salary thereafter. For 2018, 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 through April 15, 2018 and 50% of his base salary thereafter. For 2018, Mr. McMeans 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 through August 15, 2018 and 45% of his base salary thereafter.

The corporate goals established by our board of directors for 2018 were based upon commercial and financial goals. Specific goals included financial performance, progress with biopharmaceutical company collaborative development programs and market and commercialization metrics in Europe. The financial goals were weighted at 70% towards overall corporate goal achievement and the commercial goals were weighted at 30% towards overall corporate goal achievement. There was no minimum percentage of corporate goals that was required to be achieved to earn a bonus. No specific individual goals were established for any of our named executive officers for 2018.

In January 2019, our board of directors determined that the 2018 corporate goals had been achieved at an aggregate level of 75%. As a result, on January 24, 2019, our board of directors awarded the following performance-based bonuses to our named executive officers:

Executive Officer	Title	2018 Bonus Amount
Timothy B. Johnson	Chief Executive Officer	$ 166,183
John L. Lubniewski	President and Chief Operating Officer	$ 116,007
Shaun D. McMeans	Senior Vice President and Chief Financial Officer	$ 91,438

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, 2018, 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 stock 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 one to 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.

Agreements with Named Executive 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 in May 2015. The agreement sets forth certain agreed upon terms and conditions of employment. Mr. Johnson was initially entitled to receive an annual base salary of $400,000 (which has been increased, most recently in August 2018 to $450,000), an annual target performance bonus of up to 50% of his base salary (increased in August 2018 to 55% of 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.

Mr. Johnson will transition to the Company's Executive Chairman effective March 31, 2019, at which time Mr. Johnson's annual base salary will be reduced to $100,000.

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 in May 2015. The agreement sets forth certain agreed upon terms and conditions of employment. Mr. Lubniewski was initially entitled to receive an annual base salary of $293,500 (which has been increased, most recently in April 2018 to $335,000), an annual target performance bonus of up to 40% of his base salary (increased in April 2018 to 50% of 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.

Mr. Lubniewski will become the Company's President and Chief Executive Officer effective March 31, 2019, at which point his salary will increase to $385,000, and he will be eligible to receive an annual target performance bonus of up to 55% of his base salary as determined by the board of directors following analysis conducted by independent third-party consultants.

Employment Letter Agreement with Mr. McMeans. We entered into an amended and restated letter agreement with Mr. McMeans in December 2014 that replaced his previous letter agreement and became effective in May 2015. The agreement sets forth certain agreed upon terms and conditions of employment. Mr. McMeans was initially entitled to an annual base salary of $246,000 (which has been increased, most recently in August 2018 to $315,000), an annual target performance bonus of up to 40% of his base salary (increased in August 2018 to 45% of 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. McMeans' 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.

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 Mr. McMeans.

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, 2018, 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)	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	—	—	—	—
	(1)	8/06/2013	9,311	—	—	2.15	8/06/2023	—	—	—	—
	(1)	3/20/2014	43,267	—	—	2.15	3/20/2024	—	—	—	—
	(2)	12/29/2014	9,311	—	—	12.89	12/29/2024	—	—	—	—
	(2)	2/16/2016	85,314	19,686	—	2.36	2/15/2026	—	—	—	—
	(1)	2/13/2017	19,000	—	—	1.92	2/13/2027	—	—	—	—
	(2)	8/16/18	18,750	131,250	—	3.40	8/16/28	—	—	—	—
	(3)	8/16/18	—	—	—			65,624	223,122	—	—
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	—	—	—	—
	(1)	8/06/2013	13,036	—	—	2.15	8/06/2023	—	—	—	—
	(1)	3/20/2014	29,818	—	—	2.15	3/20/2024	—	—	—	—
	(2)	12/29/2014	3,724	—	—	12.89	12/29/2024	—	—	—	—
	(2)	2/16/2016	28,439	6,561	—	2.36	2/15/2026	—	—	—	—
	(1)	2/13/17	20,000	—		1.92	2/13/2027	—	—	—	—
	(2)	8/16/18	12,500	87,500	—	3.40	8/16/28	—	—	—	—
	(3)	8/16/18	—	—	—			43,750	148,750	—	—
Shaun D. McMeans	(1)	3/08/2012	8,380	—	—	2.15	3/08/2022	—	—	—	—
	(1)	2/01/2013	1,854	—	—	2.15	2/01/2023	—	—	—	—
	(1)	8/06/2013	13,036	—	—	2.15	8/06/2023	—	—	—	—
	(1)	3/20/2014	30,308	—	—	2.15	3/20/2024	—	—	—	—
	(2)	12/29/2014	2,327	—	—	12.89	12/29/2024	—	—	—	—
	(2)	2/16/2016	16,250	3,750	—	2.36	2/15/2026	—	—	—	—
	(1)	2/13/2017	18,500	—	—	1.92	2/13/2027	—	—	—	—
	(2)	8/16/18	12,500	87,500	—	3.40	8/16/28	—	—	—	—
	(3)	8/16/18	—	—	—			21,874	74,372	—	—

(1) Fully vested.

(2) Stock 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 over four years as follows: 1/16 of the award vests 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.

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 ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation (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 were designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards would 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. The exemption from the deduction limit under Section 162(m) of the Code for "performance-based compensation" has been repealed, effective for taxable years beginning after December 31, 2017.

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, 2018, option awards covering an aggregate of 1,676,802 shares of our common stock and an additional 227,707 RSU awards have been granted under the 2014 Plan and were outstanding.

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. Stock 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 stock 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, stock 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, stock 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. Stock 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, prior to the repeal of the exemption from the deduction limit under Section 162(m) of the Code for "performance-based compensation," could 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.

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; (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 stock options granted under the 2014 Plan to our named executive officers provide that vesting and exercisability of such stock 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, 2018, option awards under the 2011 Plan covering an aggregate of 349,432 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. Stock 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 stock options for a period of three months following the cessation of service. The stock 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 stock 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, stock 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 stock options granted under the 2011 Plan, including the stock 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, 2018, there were outstanding stock options under our 2001 Plan covering a total of 21,003 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 2018, 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, 2018 to each of our non-employee directors:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (1)	Option Awards ($) (2)	Total ($)
Ann F. Hanham	72,500	8,275	33,100	113,875
Harry A. George	42,500	8,275	33,100	83,875
Donnie M. Hardison	45,000	8,275	33,100	86,375
James T. LaFrance	51,250	8,275	33,100	92,625
Lee R. McCracken	43,750	8,275	33,100	85,125
Lewis J. Shuster (3)	31,250	—	—	31,250
Michelle R. Griffin (4)	18,750	—	66,200	84,950

(1) As of December 31, 2018, the aggregate number of unvested stock awards (other than options) held by our non-employee directors were: 2,500 for each of Dr. Hanham, Mr. George, Mr. Hardison, Mr. LaFrance and Mr. McCracken; Ms. Griffin did not hold any such awards. The dollar amounts in this column represent the aggregate grant date fair value of RSU awards granted in 2018. For further discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) As of December 31, 2018, the aggregate number of outstanding options to purchase our common stock held by our non-employee directors were: Dr. Hanham: 26,000, Mr. George: 28,000; Mr. Hardison: 32,000; Mr. LaFrance: 32,000; Mr. McCracken: 32,000 and Ms. Griffin: 20,000. The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2018. These amounts have been computed in accordance with FASB ASC Topic 718, using the Black-Scholes option pricing model. For further discussion of valuation assumptions, see Note 13 "Stock-based Compensation" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(3) Mr. Shuster's service on our board of directors ended in August 2018.

(4) Ms. Griffin joined our board of directors in August 2018.

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.

Pursuant to our non-employee director compensation policy, non-employee director compensation for service on our board of directors was as follows as of January 1, 2018:

- 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.

In August 2018, the non-employee director compensation policy was amended and restated, as a result of an analysis conducted by third-party independent consultants, 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 10,000 shares of our common stock and an automatic RSU award for 2,500 shares of our common stock for each non-employee director who is serving on the board of directors on the date of each annual stockholder meeting and who has served as a member of our board of directors for a minimum of six months, in each case vesting on the earliest to occur of (i) the date that is 12 months following the grant date and (ii) the following year's annual stockholder meeting; and
- upon first joining our board of directors an automatic initial option grant to purchase 20,000 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 stock 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, 2018.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) (3)	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	21,003	$ 4.48	—
2011 Equity Incentive Plan	349,432	3.45	—
2014 Equity Incentive Plan (1)	1,904,509	2.97	—
2014 Employee Stock Purchase Plan (2)	—	N/A	158,067
Equity compensation plans not approved by security holders	—	—	—
Total	2,274,944		158,067

(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, 2019, the available shares for purchase under the 2014 Plan was increased by 557,190 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 board of directors that is less than the amounts set forth in the foregoing clauses (a) and (b). On January 1, 2019, the available shares for purchase under our ESPP was increased by 139,297 shares.

(3) The number of shares to be issued upon exercise of outstanding options, RSUs, warrants and rights under the 2014 Equity Incentive Plan includes 227,707 outstanding RSU awards which have been excluded from weighted-average exercise price in column (b) above.

Principal Stockholders

The following table sets forth certain information regarding the ownership of the Company's common stock as of February 28, 2019 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 28,594,762 shares outstanding on February 15, 2019, 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		
FMR LLC (1)	3,607,849	12.6%
245 Summer Street		
Boston, MA 02210		
Stonepine Capital Management (2)	2,675,889	9.4%
919 NW Bond Street, Suite 204		
Bend, OR 97703		
Select Medical Technology and Devices Portfolio	2,392,976	8.4%
245 Summer Street		
Boston, MA 02210		
T. Rowe Price Associates, Inc.	1,999,100	7.0%
100 E. Pratt Street		
Baltimore, MD 21202		
T. Rowe Price Health Sciences Fund, Inc.	1,629,330	5.7%
100 E. Pratt Street		
Baltimore, MD 21202		
QIAGEN NV (3)	1,611,102	5.5%
Hulsterweg 82, 5912 PL		
Venlo, The Netherlands		
Directors and named executive officers		
Timothy B. Johnson (4)	460,131	1.6%
John L. Lubniewski (5)	256,334	*
Shaun D. McMeans (6)	207,244	*
Ann Hanham (7)	16,919	*
Harry A. George (8)	196,396	*
Michelle R. Griffin		
Donnie M. Hardison (9)	29,227	*
James T. LaFrance (10)	29,500	*
Lee R. McCracken (11)	22,000	*
All current executive officers and directors as a group (9 persons) (12)	1,217,751	**4.2%**

* Represents beneficial ownership of less than one percent.

(1) 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 13, 2019 with the SEC.

(2) Stonepine Capital Management, LLC, a California limited liability company is the general partner and investment advisor of investment funds, including Stonepine Capital, L.P., a Delaware limited partnership. Jon M. Plexico and Timothy P. Lynch are the control persons of the general partner. These filers have filed a Schedule 13G jointly, but not as members of a group, and each disclaims membership in a group. Each filer also disclaims beneficial ownership of the stock except to the extent of that person's pecuniary interest therein. In addition, the filing of the Schedule 13G on behalf of Stonepine Capital, L.P. should not be construed as an admission that it is, and it disclaims that it is, a beneficial owner, as defined in Rule 13d-3 under the Securities Act of 1934, of any of the stock covered by the 13G. This information is based on the Schedule 13G filed on February 13, 2019 with the SEC

(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 267,273 shares that Mr. Johnson has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options.

(5) Includes 138,412 shares that Mr. Lubniewski has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options.

(6) Includes 112,218 shares that Mr. McMeans has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options.

(7) Includes 14,615 shares that Dr. Hanham has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options

(8) Consists of (i) 144,366 shares beneficially owned by Solstice Capital II LP and (ii) 18,000 shares that Mr. George has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options. Mr. George is the managing member of Solstice Capital II LP and has joint voting and investment power over the shares held by Solstice Capital II LP.

(9) Includes 21,727 shares that Mr. Hardison has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options.

(10) Includes 22,000 shares that Mr. LaFrance has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options.

(11) Includes 22,000 shares that Mr. McCracken has the right to acquire from us within 60 days of February 15, 2019 pursuant to the exercise of stock options.

(12) The number of shares beneficially owned consists of (a) the shares described in Notes (4) through (11).

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, 2017 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."

Transactions with QIAGEN Manchester Limited and Affiliates

In November 2016, we entered into a Master Assay Development, Commercialization and Manufacturing Agreement ("Governing Agreement") with QIAGEN Manchester Limited ("QML"), and we concurrently entered into a stock purchase agreement with QIAGEN North American Holdings, Inc. ("QNAH"). Both QML and QNAH are wholly owned subsidiaries of QIAGEN N.V. Pursuant to the shares of our common stock acquired by QNAH under the stock purchase agreement, QNAH became a greater than 5% holder of our common stock.

In June 2017, we entered into a first statement of work ("SOW One") with QML under the Governing Agreement. SOW One addressed the initial activities to be performed by us and QML in support of the development and potential commercialization of a NGS-based companion diagnostic assay (the "Project") that is the subject of a sponsor project agreement between QML and a biopharmaceutical company ("Pharma One"). We amended SOW One on December 18, 2017 and March 30, 2018 in connection with the completion of initial-phase development activities under SOW One. The second amendment to SOW One relates to next-phase development activities, including assay design verification and preparation for regulatory submission, for the Project ("Next-Phase Activities"). Under SOW One, as amended, QML agreed to pay us low, single-digit millions of dollars for the Pharma One development work performed under the SOW, and we and QML agreed to share any net profits resulting from performance of the development work as determined pursuant to the Governing Agreement. QML also agreed to pay us milestone payments up to an amount in the low, single-digit millions of dollars in the aggregate upon the achievement of certain development milestones during the Next-Phase Activities. On May 16, 2018, we received written notice from QML that it had terminated SOW One following the termination of the Project by Pharma One. For additional details regarding the terms of SOW One, please refer to Note 16 to our consolidated financial statements contained in this Annual Report.

In connection with SOW One, the Governing Agreement was amended to provide that neither party may terminate SOW One or the Governing Agreement to the extent it relates to SOW One in the event of a change of control.

In October 2017, we entered into a second statement of work ("SOW Two") under the Governing Agreement with QML. SOW Two was made effective as of June 2, 2017 ("Onset Date"), and was amended on August 7, 2018, August 13, 2018 and September 27, 2018. SOW Two addresses development activities conducted by us and QML since the Onset Date and those expected to be further conducted by parties in connection with a sponsor project agreement, dated June 2, 2017, between QML and Bristol-Myers Squibb. The initial-phase investigational use only ("IUO") development activities under SOW Two have been completed and the first two amendments of SOW Two relate to the next phases, which include the use of the IUO assay developed in the initial-phase in a retrospective clinical trial and in additional disease indications. The third amendment to SOW Two provides that profit sharing relating to the original development activities and the development activities contemplated by the first SOW Two amendment will, in each case, commence upon the later of (i) the third amendment effective date, which is September 27, 2018, and (ii) the completion of the respective development activities, rather than at the end of each calendar quarter, provided that such modification to the profit-sharing commencement date only applies to development activities that had not yet been subject to profit-sharing as of the third amendment effective date. Under SOW Two, as amended, QML has agreed to pay us mid-single digit millions of dollars for the development work performed and expected to be performed by us and QML under SOW Two. In addition, we will share in any net profits (as determined under the Governing Agreement) generated during the work on an approximately quarterly basis throughout the term of SOW Two, except as otherwise specified in the third amendment to SOW Two. For additional details regarding the terms of SOW Two, please refer to Note 16 to our consolidated financial statements contained in this Annual Report.

In January 2018, we entered into a third statement of work ("SOW Three") under the Governing Agreement with QML. SOW Three addresses the development activities for a NGS-based clinical-trial assay ("SOW Three Project") in connection with a sponsor project agreement between QML and a pharmaceutical company ("Pharma Three"). We amended SOW Three on September 21, 2018 in connection with the completion of initial assay development activities under SOW Three. The first amendment to SOW Three provides for the development of an IUO assay, subsequent retrospective testing of clinical trial samples, design verification and, subject to satisfactory achievement of relevant performance and regulatory milestones, regulatory submissions in the United States and European Union necessary for the commercialization of a companion diagnostic for a corresponding Pharma Three drug. Under SOW Three, as amended, QML has agreed to pay us low, single-digit millions of dollars for the development work performed and expected to be performed by us and QML under SOW Three. In addition, we will share in any net profits (as determined under the Governing Agreement) generated during the work on an approximately quarterly basis throughout the term of SOW Three. For additional details regarding the terms of SOW Three, please refer to Note 16 to our consolidated financial statements contained in this Annual Report.

In October 2017, we issued a subordinated convertible promissory note (the "QNAH Convertible Note") to QIAGEN North American Holdings, Inc. ("QNAH") in the principal amount of $3.0 million against receipt of cash proceeds equal to such principal amount. The QNAH Convertible Note bears simple interest at the rate of 3.0% per annum and matures on October 26, 2020. Our indebtedness under the QNAH Convertible Note is expressly subordinated in right of payment to the prior repayment in full of our indebtedness under our Growth Term Loan. QNAH may elect to convert all or any portion of the outstanding principal balance of the QNAH Convertible Note and all unpaid accrued interest thereon at any time prior to the maturity date into shares of our common stock at a conversion price of $3.984 per share.

Since October 26, 2017, the outstanding principal amount of the QNAH Convertible Note has remained at $3.0 million. No accrued interest has been paid and all accrued interest will become due on the maturity date of October 26, 2020.

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 2018 and 2017.

	December 31,	
	2018	2017
Fee Category		
Audit fees (1)	$ 419,213	$ 551,265
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total fees	$ 419,213	$ 551,265

(1) Audit fees consist of fees for professional services provided primarily in connection with the annual audit of our consolidated financial statements, quarterly reviews and services associated with SEC registration statements and other documents issued in connection with securities offerings including comfort letters and consents.

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) Consolidated Financial Statements - The consolidated financial statements filed as part of this Annual Report on Form 10-K are listed on the Index to Consolidated 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 consolidated 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 immediately preceding the signature page to this Annual Report on Form 10-K are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

Exhibit Index

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

Exhibit Number	Description
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).
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 Quarterly 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 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).
10.10	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).
10.11	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).
10.12*	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).
10.13*	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).
10.14	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).
10.15	HTG Molecular Diagnostics, Inc. Amended and Restated Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2016).
10.16*	Master Assay Development, Commercialization and Manufacturing Agreement, dated November 16, 2016, by and between Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 23, 2017).
10.17	Controlled Equity Offering Sales Agreement, by and between the Registrant and Cantor Fitzgerald & Co., dated April 13, 2017 (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the SEC on April 13, 2017).
10.18	Registration Rights Letter Agreement, effective June 2, 2017, by and between the Registrant and Novo Holdings A/S (f/k/a Novo A/S) (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on August 8, 2017).

Exhibit Number	Description
10.19*	Amended and Restated Development and Component Supply Agreement, effective May 31, 2017, by and between the Registrant and Illumina, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on August 8, 2017).
10.20	First Amendment to Master Assay Development, Commercialization and Manufacturing Agreement, dated June 14, 2017, by and between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on August 8, 2017).
10.21*	Statement of Work No. 1, dated June 14, 2017, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on August 8, 2017).
10.22*	First Amendment to Statement of Work No. 1, dated December 18, 2017, under Master Assay Development Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K (File No. 001-37369) filed with the SEC on March 23, 2018).
10.23*	Second Amendment to Statement of Work No. 1, dated March 30, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2018).
10.24*	Statement of Work No. 2, dated October 26, 2017, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 23, 2018).
10.25*	Statement of Work No. 3, dated January 12, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on May 10, 2018).
10.26*	First Amendment to Statement of Work No. 3, dated September 21, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on November 8, 2018).
10.27	First Amendment to Statement of Work No. 2, dated August 7, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on November 8, 2018).
10.28	Second Amendment to Statement of Work No. 2, dated August 13, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on November 8, 2018).
10.29	Third Amendment to Statement of Work No. 2, dated September 27, 2018, under Master Assay Development, Commercialization and Manufacturing Agreement between the Registrant and QIAGEN Manchester Limited (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on November 8, 2018).
10.30*	Supplement Agreement, dated October 26, 2017, by and among the Registrant, QIAGEN Manchester Limited and Bristol-Myers Squibb Company, as amended (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 23, 2018).
10.31	Amendment to the Supplement Agreement, dated August 13, 2018, by and among the Registrant, QIAGEN Manchester Limited and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on November 8, 2018).

Exhibit Number	Description
10.32	Credit and Security Agreement (Term Loan) by and among the Registrant, the lenders party thereto from time to time and MidCap Financial Trust, as agent, dated March 26, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on May 10, 2018).
10.33	Credit and Security Agreement (Revolving Loan) by and among the Registrant, the lenders party thereto from time to time and MidCap Funding IV Trust (assignee of MidCap Financial Trust), as agent, dated March 26, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on May 10, 2018).
10.34	Second Amendment to Lease Agreement (Suite 100 – Administration – to include Suite 200), dated January 28, 2019, by and between Pegasus Properties, L.P. and the Registrant.
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

+ Indicates management contract or compensatory plan.

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

Item 16. Form 10-K Summary.

None.

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 7, 2019

By: /s/ Timothy B. Johnson
Timothy B. Johnson
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 Timothy B. Johnson	Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer)*	March 7, 2019
/s/ Shaun D. McMeans Shaun D. McMeans	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 7, 2019
/s/ Ann F. Hanham Ann F. Hanham	Chair of the Board of Directors	March 7, 2019
/s/ Harry A. George Harry A. George	Member of the Board of Directors	March 7, 2019
/s/ James T. LaFrance James T. LaFrance	Member of the Board of Directors	March 7, 2019
/s/ Lee R. McCracken Lee R. McCracken	Member of the Board of Directors	March 7, 2019
/s/ Michelle R. Griffin Michelle R. Griffin	Member of the Board of Directors	March 7, 2019
/s/ Donnie M. Hardison Donnie M. Hardison	Member of the Board of Directors	March 7, 2019

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