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, 2020

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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**HTGM**	**The Nasdaq Stock Market LLC**

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 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 the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the 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 30, 2020 (the last business day of the Registrant's most recently completed second fiscal quarter), was $47,829,280.

The number of shares of Registrant's Common Stock outstanding as of March 15, 2021 was 6,214,400.

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PART I

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

Forward-Looking Statements

This Annual Report on Form 10-K, including the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," may contain forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "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 sufficient revenue or raise additional capital to meet our working capital needs;
- our ability to generate revenue from our products and services and drive revenue streams;
- the impact of the COVID-19 pandemic on our business;
- our ability to develop new technologies to expand our product offerings, including direct-target sequencing for detection of mutations from expressed RNA (such as single-point mutations and gene rearrangements, including gene fusions and insertions) and a transcriptome product;
- 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;
- our ability to secure regulatory clearance or approval, domestically and internationally, for the clinical use of our products;
- 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, 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.

RISK FACTOR SUMMARY

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our common stock.

- 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.
- If we are unable to successfully commercialize our products, our business may be adversely affected.
- If our HTG EdgeSeq platform and proprietary profiling panels fail to achieve and sustain sufficient market acceptance, or we are not able to continue to expand our service or collaborative relationships with biopharmaceutical customers, either directly or through a collaboration partner, we will not generate expected revenue, and our prospects may be harmed.
- Public health epidemics, pandemics or outbreaks, including the recent coronavirus pandemic, could adversely affect our business.
- 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 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.
- 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.
- Our strategy of developing companion diagnostic products may require large investments in working capital and may not generate any revenue.
- 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.
- 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.
- 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.
- 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, which 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 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.
- 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.
- Payments under the instruments governing our indebtedness may reduce our working capital. In addition, a default under our SVB Term Loan or cross default under our PPP Loan could cause a material adverse effect on our financial position.
- 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.
- 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.
- If we are unable to protect our intellectual property effectively, our business will be harmed.
- We may need to depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling some of our products.

Item 1. Business.

Overview

We are a commercial stage RNA platform-based life sciences company focused on advancing the promise of precision medicine. Our proprietary NGS-adapted chemistry and HTG EdgeSeq platform automate sample processing and can quickly, robustly and simultaneously profile hundreds or thousands of molecular targets using a relatively small amount of biological sample, in liquid or solid forms. Our products include instruments, consumables and software that combine to form our HTG EdgeSeq platform. Our menu of HTG EdgeSeq molecular profiling panels is automated on our HTG EdgeSeq platform, applying genomic sequencing tools to quickly generate gene expression data using our simplified workflow for customers.

Our objective is to establish our solutions as the standard in molecular profiling, companion diagnostic 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 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, including simplified bioinformatics. Our 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.

Our HTG EdgeSeq technology solution is currently being used in two complementary ways to advance precision medicine. Biopharmaceutical companies, academic institutions and other translational research centers purchase our HTG EdgeSeq technology to discover and validate biomarkers and develop molecular subtypes which can identify patient populations most likely to respond to certain therapies. Our HTG EdgeSeq platform, assays and software facilitate customer analysis of gene expression profiles from a wide variety of sample types to accelerate discovery, support translational applications and evaluate target biomarkers for companion diagnostics. Our HTG EdgeSeq Reveal software is a complementary technology that supports our customers in interrogating and visualizing HTG EdgeSeq data, and gaining insights into complex biology using gene signatures that enable a greater understanding of the disease heterogeneity and the tumor microenvironment.

In addition to purchasing our technology for use in their facilities, customers can also obtain the advantages of our technology by contracting with one of our certified service providers or Preferred Academic Centers of Excellence (“PACE”) partners, or through our Tucson, Arizona-based VERI/O laboratory for sample processing and custom assay development service offerings. Our PACE program has established a network of small and large academic centers committed to expanding the utility of our technology in distinct areas of cancer, neurodegenerative and auto-immune disease research. PACE partners support this effort by establishing a consortium of users, generating useful data demonstrating the utility of our technology and conducting technology workshops to raise awareness of our technology and its applications.

Pre-clinical services, including custom assay design and sample processing services provided by our VERI/O laboratory employees, allow our customers to identify and validate biomarker signatures across their drug portfolios or patient cohorts more efficiently. Our VERI/O laboratory is a high-volume molecular laboratory focused solely on providing high-quality data from our proprietary molecular profiling technology. These services provide our customers expedited access to our technology at a competitive price. For our biopharmaceutical company customers, we offer an end-to-end solution leveraging a single technology from discovery to diagnostics. Through collaboration with biopharmaceutical company customers, we believe we are uniquely positioned to provide comprehensive services to design, develop and manufacture custom targeted assays with complex molecular diagnostic signatures as investigational use only (“IUO”) assays for use in global prospective or retrospective clinical trials. Our expertise in medical device design control and global regulatory submissions, coupled with our ISO 13485:2016 certified quality system, enable us to support potential companion diagnostic (“CDx”) programs. Although our initial focus primarily has been in oncology, we offer customers a full solution from biomarker discovery to deployment of CDx assays across numerous 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.

Our product and service offerings currently result in recognition of two primary sources of revenue:

- product and product-related services revenue from the sale of research use only (“RUO”) and profiling products with a CE Marking as defined by the Requirements of European Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices (“CE/IVD”), sample processing services and custom assay design services; and

- revenue from collaborative development services for companion diagnostic development programs for biopharmaceutical companies.

We believe RNA-based applications represent a large and growing market with significant, unmet needs where our HTG EdgeSeq platform has allowed us to demonstrate competitive advantages. We further believe that our platform technology can enable gene expression profiling growth to accelerate as we make NGS-based gene expression analysis easier and more sample sparing.

We have experienced a significant slowing of product and product-related services revenue since March 2020, and we believe this period of reduced revenue will continue through at least the first half of 2021 due to continued disruptions to our customers' businesses from the pandemic and, in many instances, their prioritization of projects in areas focus related to COVID-19. We have also experienced limited delays in our development efforts as a result of stay-at-home orders and our efforts to prioritize the safety of our employees during this pandemic. However, all of our 2020 key development milestones were met and high priority development efforts continued, including extensive experiment study planning and analysis, despite the numerous operational challenges we have faced. We believe the COVID-19 pandemic will continue to impact our productivity, supply chains, distribution networks and other areas of our operation as the pandemic continues to disrupt our business and the businesses of our vendors, partners and customers.

Our Strategy

Our objective is to establish our solutions as the standard in gene expression for molecular profiling, and to make their benefits accessible to all molecular labs from research to the clinic. We believe HTG EdgeSeq technology is a platform that we can leverage into three primary revenue verticals: RUO profiling, molecular diagnostics and companion diagnostic collaborations. The key components of our strategy are:

- *Expand our position in translational medicine with our RUO molecular profiling products.* We believe the market for gene expression analysis for translational medicine is large and growing quickly. We have built targeted panels in oncology, immuno-oncology, immune response and micro-RNA that enable scientists to look at gene expression patterns to identify molecular subtypes, study key pathways and to discover and validate biomarker hypotheses to help drive precision medicine. In 2020, we expanded the utility of these panels by adding new applications to interrogate the tumor micro-environment such as tumor inflammation and immunophenotyping signatures in our HTG EdgeSeq Reveal software. Next, we expect to continue development of our transcriptome product, which is expected to measure approximately 20,000 RNA targets, covering the entire human transcriptome, with commercial launch of an RUO product currently expected for the third quarter of 2021. We expect this product to enable gene expression analysis of the transcriptome from significantly less sample input and from lower quality samples. We further expect this product to expand our product offerings outside of oncology and autoimmune and into markets such as transplant and diabetes.
- *Partner with other diagnostic developers to develop, or develop independently, molecular diagnostic panels with high medical utility*. Our HTG EdgeSeq platform technology was developed with features that we believe solve many of the challenges facing NGS-based assays and workflows. We plan to leverage our core HTG EdgeSeq technology to partner with other test developers and Clinical Laboratory Improvement Amendments ("CLIA") certified labs to develop molecular diagnostic tests or to enable laboratory developed test ("LDT") development. We further expect the transcriptome product to be an additional platform on which we will partner with these customers and build proprietary HTG diagnostic panels.
- *Re-establish companion diagnostics collaborations with biopharmaceutical companies.* We believe collaborations with biopharmaceutical companies with late-stage drug development programs have the potential to lead to us generating companion diagnostic consumables revenue. As of December 31, 2020, our technology and products were used in 50 active 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 profiling tests that can provide important biomarker information in emerging areas of immuno-oncology, autoimmune and other disease areas. In addition, once available, we expect to develop and market a clinical grade transcriptome product as a new universal CDx platform for gene expression profiling to biopharma customers. In 2020, we signed a new 10-year non-exclusive agreement with QIAGEN Manchester Limited ("QML") to leverage its global commercial expertise and global distribution reach specifically for CDx assays. We believe this further strengthens our ability to partner with biopharma customers for potential CDx opportunities.

- *Establish our systems workflow as the best solution for RNA clinical sequencing*. We intend to continue to establish our technology as the best complementary 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. and Thermo Fisher Scientific, Inc. 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 disease states and liquid biopsies*. In 2020, we released several new applications focused on oncology to interrogate the tumor micro-environment, such as tumor inflammation and immunophenotyping signatures available in our HTG EdgeSeq Reveal software. We expect continued development of these new applications will allow us to reach new customers focused on additional disease areas and markets. Customers are now using our platform technology in autoimmune disorders, infectious disease and diabetes. We have also shown feasibility of being able to measure RNA in exosomes, which we believe positions us to expand into liquid biopsy applications. We continue to assess and broaden the utility of our platform technology, and strategically seek partners and collaborators who may be interested in additional areas outside of our core focus area of oncology.

Our Market Opportunities

Cancer Molecular Profiling and Genomics in Life Science Research

Molecular profiling is the analysis of biomarkers, including DNA, 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 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 supplier market for RNASeq is estimated to be approximately $1.0 billion and growing annually at 10-20%. The gene expression component of that market is estimated to be approximately $820.0 million and growing at the same rate. With these metrics in mind, we expect our target market, NGS-based gene expression profiling, to be between $1.3 billion and $2.0 billion by 2024.

Therapy Driven Diagnostics - Companion Diagnostics

The World Health Organization estimates that cancer will lead to the death of 11.5 million people by 2030. As a result, biopharmaceutical companies are aggressively deploying biomarker driven strategies to improve the response rates to existing and new drugs in development as well as combination therapies. These companies are looking for technology solutions that can more effectively identify the biological root causes of disease and aid the discovery of 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 currently approximately 3,100 oncology clinical trials, approximately 24% of which are interrogating RNA. This percentage has more than doubled since 2014, and we believe this percentage will approach 50% by 2025.

Molecular Diagnostics – NGS-based Workflows

Complexities and Challenges of Molecular Diagnostics Today

Currently, molecular profiling is typically 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 chemistry provides a sensitive and efficient method for analyzing RNA as it eliminates the need for nucleic acid extraction, reverse transcription, complicated bioinformatics steps and other complex processes. We designed and developed our automation platform and software analysis tools to optimize the capabilities of our chemistry, provide fast turnaround time and enable ease of use to molecular labs. Our chemistry and automation platform 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 platform 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 in a single testing workflow that can use NGS detection for quantitative measurement.

We believe we are well positioned with the following key product benefits:

- *Optimize sample utilization*. Our platform can analyze several thousand genes from extremely small sample volumes such as a single five-micron section of tissue or 15 microliters of plasma or serum. With the launch of our transcriptome panel, the analysis plex increases 10 times, while maintaining minimal sample input requirements. 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 volumes will be a significant driver of adoption of our technology and systems.
- *Compatibility with multiple sample types*. Our proprietary technology allows customers to profile and unlock molecular information from a wide variety of biological samples such as formalin fixed paraffin embedded ("FFPE") tissue, cells, whole 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 technology 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 and expressed RNA gene rearrangements (such as gene fusions and insertions), 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 ("RT-qPCR"), 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 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 chemistry is highly specific and sensitive, meaning it 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 technology is 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 platform 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 HTG EdgeSeq Reveal 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 generated 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 NGS;
- Industry partnerships with leading NGS companies enabling the development and commercialization of next-generation molecular diagnostics utilizing the combined power of HTG EdgeSeq platform 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 CDx assays; and
- A highly experienced senior management team.

Current Commercial Panels Offered on the HTG EdgeSeq Platform

We currently market proprietary molecular profiling panels targeting early and 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:

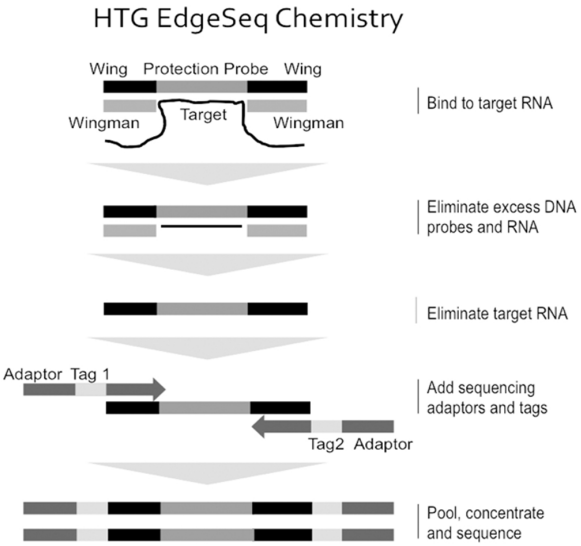
- *HTG EdgeSeq Oncology Biomarker Panel*. This RNA expression panel measures the expression of up to 2,549 genes associated with tumor biology for profiling tumor tissues, analyzing cancer pathways, identifying therapeutic targets and drug response markers, and identifying new biomarkers across both 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 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.
- *HTG EdgeSeq miRNA Whole-Transcriptome Assay*. Human microRNAs (“miRNA”) 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 miRNAs, allowing new, potentially clinically relevant miRNA profiles to be discovered. Our ability to efficiently profile small FFPE samples or as little as 15 µL of plasma or serum is a significant differentiator in the rapidly growing miRNA 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 diffuse large B-cell lymphoma ("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 activated B-cell like ("ABC"), germinal center B-like ("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 DLBCL Cell of Origin Assay*. DLBCL tumors are frequently classified into either ABC or GCB subtypes 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 subtype. With many of the large number of new DLBCL-targeting drugs appearing to have greater efficacy in one of the subtypes, a need for a reliable, FFPE-based cell of origin classification assay has emerged. This product is labeled RUO and is available as an IUO for use in late-stage drug programs to stratify patients.
- *HTG Lung Fusions Assay*. The HTG EdgeSeq Lung Fusions Assay detects fusions common in non-small cell lung cancer ("NSCLC"). Using a single section of FFPE tissue, the automated, HTG EdgeSeq chemistry uses the dynamic range of the Thermo Fisher Ion Torrent Ion S5 sequencer to detect fusions in small samples such as needle core biopsies.
- *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 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 Immune Response Panel*. The HTG EdgeSeq Immune Response Panel leverages the sensitivity and dynamic range of NGS to measure genes implicated in a variety of autoimmune diseases as well as immune response to infectious disease, including COVID-19. The panel measures 2,002 transcripts in a single well, allowing users to obtain a broad profile of genes associated with autoinflammatory, autoimmune and infectious disease, and enables multiplex profiling from FFPE and PAXgene samples.
- *HTG Mouse mRNA Tumor Response Panel.* The HTG EdgeSeq Mouse mRNA Tumor Response Panel measures 1,659 mouse mRNA targets to measure genes implicated in preclinical mouse models of human disease. Built around core signaling pathways and immune response mechanisms in oncology and other disease states, the HTG EdgeSeq mRNA Tumor Response Panel enables multiplex profiling from a variety of sample types, including FFPE, cell lines and extracted RNA samples. Applications include modeling oncogenesis, studying the immune response to mouse and patent-derived xenografts, and investigational therapeutic response studies.

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 platform.



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 have demonstrated feasibility on our technology working with panels as large as 22,000 genes. 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 RT-qPCR 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 RT-qPCR, our chemistry does not require extraction or cDNA synthesis. Compared to traditional RNA sequencing, our chemistry does not require extraction, cDNA synthesis, shearing, rRNA depletion, ligation, adenylation, or size selection. We believe that the accumulation of these steps required by other technologies results in amplification of biases, sample degradation and increased opportunities for technician error.

HTG Instrument Platform

Our instrument and assays were developed internally and are manufactured in Tucson, AZ under ISO 13485:2016 certified procedures 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 as few as 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 consists of a processor (shown above), 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 instrument 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 liquid handling within the instrument is 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 platform 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 from one to 96 samples in a single batch.

In addition to direct sales of our systems, we utilize several alternative arrangements to provide customer access to our platform. 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 prior to acquisition. 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 and volume over the term of the agreement or allow customers to rent our instrument for a monthly fee. As of December 31, 2020, we had an installed base of 68 instruments (consisting of 51 systems sold, five covered under reagent rental or standard rental agreements, five evaluation units and seven systems with key opinion leaders).

Opportunities for Comprehensive Molecular Profiling in Diagnostics

We are currently developing what we believe will be a cornerstone transcriptome product for use in both RUO molecular profiling and as a platform technology for clinical and companion diagnostics. We are initially focused on partnering with other content providers who want an improved RNA GEP platform technology for their tests. We expect to partner with CLIA certified laboratories in the U.S. and major medical centers in Europe. We also expect to position the transcriptome product as a universal RNA GEP platform for biopharmaceutical company customer biomarker validation and CDx development.

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 immunophenotyping 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 platform. We expect this to require substantial effort from our research scientists and the use of various laboratory equipment, supplies and materials, which all together represent the most significant costs that we expect to incur in connection with the development of these applications and profiling panels.

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, 2020, our research and development team consisted of 29 employees across the disciplines of research and development scientist, platform development and bioinformatics.

Our development efforts are primarily focused on the continued development and release of our planned transcriptome panel, which includes multiple advancements in our proprietary chemistry and associated workflow. Our development team is also responsible for clinical assay development services being performed for biopharmaceutical company customers. 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 through distributors in parts of Europe and other countries. As of December 31, 2020, our U.S. sales and marketing organization consisted of 16 employees including seven in direct sales or sales management, four in sales support and five in marketing. In addition to our U.S. sales team, as of December 31, 2020, 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 Austria, Belgium, France, Germany, Luxembourg, the Netherlands, the United Kingdom and Switzerland, with distributors in Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, Hungary, Ireland, Israel, Italy, Kosovo, Leetonia, Lithuania, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

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 platform, 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 13485:2016 standards. We believe that our existing manufacturing capacity is sufficient to meet our needs for at least the next several years.

We require a wide variety of raw materials, electronic and mechanical components, chemical and biochemical materials and other supplies to manufacture our products. While multiple commercial sources provide the majority of these required components and supplies, we currently rely on a single supplier to manufacture a subcomponent used in our HTG EdgeSeq instrument. As part of our standard supply management process, we continuously monitor material availability, vendor status and supply chain disruptions to identify and mitigate potential risks by expanding material and source alternatives. In addition, to manage potential risks arising from use of the single source subcomponent supplier, we believe that, if necessary, we could identify and qualify a second supplier for this part. In addition, while we attempt to keep our inventory at minimal levels, we closely monitor inventory of this subcomponent and purchase incremental inventory in this area as circumstances warrant to protect our supply chain. If the capabilities of our suppliers and subcomponent manufacturers are limited or stopped, due to the COVID-19 pandemic, disasters, quality, regulatory or other reasons, it could negatively impact our ability to manufacture our products.

Instruments

We assemble and test our HTG EdgeSeq instruments at our Tucson, Arizona facility. Instrument component vendors are qualified under our quality system 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 manufacture and test 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 produce 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 Abbott Molecular, Affymetrix, Inc., Agilent Technologies, Inc., BioRad Laboratories, Invitae (acquired by ArcherDx, Inc.), Fluidigm Corporation, Illumina, Inc., Luminex Corporation, NanoString Technologies, Inc., Personal Genome Diagnostics, entities owned and controlled by QIAGEN N.V., Roche Diagnostics, a division of the Roche Group of companies, and Thermo Fisher Scientific, Inc.;
- Centralized CLIA certified labs offering molecular profiling and gene expression tests as laboratory-developed tests (“LDTs”) such as Caris, Inc., Exact Sciences, Inc., Guardant Health, Inc., Foundation Medicine, Inc., NeoGenomics, Inc., Personalis, Inc. and Trovagene, Inc.; and
- Decentralized CLIA certified labs developing LDTs locally such as major cancer centers.

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

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

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 platform 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 large 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, 2020, our patent portfolio included 12 patent families that, collectively, consisted of six issued U.S. patents, 51 granted foreign patents (variously in Australia, Canada, China, Japan, France, Germany, Italy, Spain, and United Kingdom), and 16 patent applications pending in the United States and foreign jurisdictions (including one allowed in Canada). 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 COO 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, 2020. The HTG EdgeSeq method patents will expire in April 2032. Our portfolio also included 16 applications as of December 31, 2020, including six for our direct-target sequencing (V2) HTG EdgeSeq methods, six for our DLBCL subtyping methods, and a patent cooperation treaty application 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 into 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 ("NuvoGen obligation"). 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 agreed to pay NuvoGen aggregate cash compensation of $15.0 million. On an annual basis we are currently obligated to pay the greater of $0.4 million or 6% of our annual revenue, until the total aggregate cash compensation paid to NuvoGen under the agreement totals $15.0 million. Interest on the remaining unpaid obligation has been accrued since January 1, 2019 and compounds 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.

SVB Term Loan

On June 24, 2020, we entered into a Loan and Security Agreement (the "Loan Agreement"), with Silicon Valley Bank ("SVB"), as lender, which provides a secured term loan in the principal amount of $10.0 million (the "SVB Term Loan"). The proceeds from the SVB Term Loan were fully funded on the June 25, 2020. The proceeds from the SVB Term Loan, together with cash on hand, were used to repay in full all outstanding amounts and fees due under the Credit and Security Agreement (Term Loan) and Credit and Security Agreement (Revolving Loan) entered into with MidCap Financial Trust, as agent (the "MidCap Credit Facility") and a subordinated convertible promissory note to QIAGEN North American Holdings, Inc. (the QNAH Convertible Note"). Our obligations under the SVB Term Loan are secured by a security interest in substantially all of our assets, excluding intellectual property (which is subject to a negative pledge).

The SVB Term Loan bears interest at a floating rate equal to the greater of 2.5% above the Prime Rate (as defined in the Loan Agreement) and 5.75%. Interest on the SVB Term Loan is due and payable monthly in arrears. The SVB Term Loan allows for interest-only payments through June 30, 2021. The interest only period may be extended for six months upon the achievement of an equity milestone as fully defined in the Loan Agreement. The ultimate interest-only period will be followed by equal monthly payments of principal and interest through the maturity date of December 1, 2023.

Prepayments of the SVB Term Loan, in whole or in part, will be subject to early termination fees of up to 3% and we will be required to pay a final fee equal to 8% of the principal amount of the SVB Term Loan upon termination of the Loan Agreement.

The Loan Agreement contains customary affirmative covenants and customary negative covenants limiting our ability and the ability of our 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. We must also comply with a financial covenant requiring us to maintain unrestricted cash at an account with SVB of not less than the greater of (i) $12.5 million and (ii) an amount equal to six times the amount of our average monthly Cash Burn (as defined in the Loan Agreement) over the trailing three months.

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 consumables 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. In the United States, claims for Medicare coverage are processed by private Medicare Administrative Contractors ("MACs") such as Novitas and Cahaba on behalf of the Centers for Medicare & Medicaid Services ("CMS"), 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. We believe that establishment of 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. Our success 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. 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 U.S. and ex-U.S. 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 could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

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 premarket approval ("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. We believe that our companion diagnostic tests under development would be eligible for the less burdensome 510(k) regulatory pathway.

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. 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," 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.

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 the device studies.

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;
- 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;
- 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 most 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. 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.

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 premarket 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 CE/IVD marked 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, false claims, data privacy and security, and transparency 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. These laws include the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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 civil False Claims Act;
- the federal civil and criminal false claims, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal physician self-referral statute, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiology assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require biotechnology companies to report information on the pricing of certain drug products, state and local laws that require the registration of pharmaceutical sales representatives, and state and foreign laws that govern 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. For example, the EU has established its own data security and privacy legal framework, including the 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. In addition, 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. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches.

Healthcare Reform

There have been and we anticipate that there will be healthcare reform measures that may be adopted in the future that may result in more rigorous coverage criteria and additional downward pressure on the reimbursement for healthcare products and services. For example, the ACA, which substantially changed healthcare financing and delivery by both governmental and private insurers, remains subject to challenge. The U.S. Supreme Court is currently reviewing the constitutionality of the ACA, although it is unclear when a decision will be reached. It is possible that additional governmental action will be taken in response to the COVID-19 pandemic. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

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, 2020, we had 83 full-time and one part-time employee, of which 18 are employed in administration, 20 in manufacturing and operations, 18 in research and development, five in regulatory and quality affairs, and 23 in direct sales and marketing. Of these employees, eight 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 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.

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 $20.9 million and $19.3 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $191.2 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 new proprietary HTG EdgeSeq panels and products, and the commercialization of our HTG EdgeSeq platform 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.

If we are unable to successfully commercialize our products, our business may be adversely affected.

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 platform 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 on our HTG EdgeSeq platform, 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. 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. If we do not build and maintain 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 platform and proprietary profiling panels fail to achieve and sustain sufficient market acceptance, or we are not able to continue to expand our service or collaborative relationships with biopharmaceutical customers, either directly or through a collaboration partner, we will not generate expected revenue, and our prospects may be harmed.

We are currently focused on selling our HTG EdgeSeq platform 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 platform 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 U.S. Food and Drug Administration (“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 at 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 a collaboration partner, 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, a collaboration partner may take certain actions that could negatively impact the development, utility and marketability of the applicable diagnostic tests. For example, a collaboration partner could fail to satisfy or fall behind in its obligations to us or to the biopharmaceutical company for which we develop a companion diagnostic test, which may delay development, regulatory approvals, market development and/or commercialization of the applicable companion diagnostic test.

Our agreement with QML is non-exclusive and, in the future, either party may be unwilling to partner with the other, and we may be unable to implement a feasible partnering relationship for the development, manufacture, marketing and/or commercialization of companion diagnostic assays on acceptable terms, or at all. If we are unable to implement such a relationship, our efforts to develop, manufacture and commercialize companion diagnostic assays may be significantly delayed and limited in scale, or may not occur at all. Any of these events could limit our diagnostic test sales and revenue and have a material adverse effect on our business, operating results and financial condition.

The recent coronavirus pandemic has adversely affected our business and is expected to have an impact on our business for the foreseeable future.

Our business, including our workforce, supply chain and customer base, has been adversely affected by the effects of the COVID-19 pandemic.

The COVID-19 pandemic has caused several countries to implement quarantines and/or significant restrictions on travel. In addition, affected regions, including several states within the United States, have implemented work restrictions that prohibit many employees from going to work. Moreover, the COVID-19 pandemic has resulted in business closures and a substantial reduction in economic activity in the United States and worldwide.

While significant uncertainty remains as to the future impact of the COVID-19 pandemic on our operations, and on the global economy as a whole, the COVID-19 pandemic had a negative impact on our product and product-related services revenue and collaborative development services revenue in 2020. We experienced a significant slowing of revenue generation beginning in March 2020 as a result of the COVID-19 pandemic, and we believe this period of reduced revenue will continue into 2021 due to disruptions to our customers' businesses as a result of the pandemic. The extent of this impact is likely to vary from customer to customer depending upon how they are directly or indirectly impacted by local stay-at-home orders and other social distancing measures, priorities for the customers when the immediate impacts of the pandemic have passed, and the workforce and supplier impacts that each customer has experienced during the pandemic.

In March 2020, most of our workforce began working from home either all or substantially all of the time. The effects of the stay-at-home orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our development programs and regulatory timelines and negatively impact our commercial activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, these widespread outbreaks of illness could adversely affect our workforce resulting in serious health issues and absenteeism.

It is also possible that the COVID-19 pandemic will continue to impact our workforce, supply chains or distribution networks or otherwise impact our ability to conduct sample processing services and custom assay design services and our ability to provide collaborative development services for companion diagnostic development programs. Governmental mandates may require forced

shutdowns of our facilities for extended or indefinite periods. Pandemic outbreaks, including the coronavirus, could also substantially interfere with general commercial activity related to our supply chain and customer base, which could have a material adverse effect on our financial condition, results of operations, business or prospects. Restrictions resulting from the COVID-19 pandemic may disrupt our supply chains or distribution networks or limit our ability to obtain sufficient materials for our consumables or instruments and may disrupt our ability to process customer samples or perform collaborative development services. Further, to the extent our customers' businesses are adversely affected by the pandemic, they might delay or reduce purchases from us or collaborative development projects with us, which could adversely affect our results of operations.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our customers' businesses, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, financial position and liquidity.

Our business operations might be disrupted or adversely affected by catastrophic events.

We manufacture our HTG EdgeSeq instrument and consumable products 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 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. In addition, natural disasters or other catastrophic events in various parts of the world, including interruptions in the supply of natural resources, political and governmental changes, disruption in transportation networks or delivery services, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, earthquakes, wars and public health issues could disrupt our operations or those of our collaborators, contractors and vendors or contribute to unfavorable economic or other conditions that could adversely impact us.

We will 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 platform, proprietary consumables, related services and collaborative development service arrangements with biopharmaceutical company customers. We currently anticipate that our cash and cash equivalents may be sufficient to enable us to fund our operations for at least the next 12 months. However, we will need to obtain additional funds to finance our operations in the future, and we could spend our available financial resources much faster than we currently expect. These circumstances raise substantial doubt about our ability to continue as a going concern. Additional capital may not be available at such times or amounts as needed by us. Historically we have financed our business in part by access to the capital markets. General market conditions resulting from the ongoing issues arising from the COVID-19 pandemic, as well as market conditions affecting companies in the life sciences industry in general, may make it difficult for us to seek financing from the capital markets on attractive terms, or at all. 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.

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, one customer accounted for 11% of our revenue for the year ended December 31, 2020, and two customers each accounted for 9% of our accounts receivable balance as of December 31, 2020. If orders from our top customers are discontinued and we are unable to establish new projects or continue to expand our customer base, our revenue in future periods may materially decrease. In addition, we experienced a significant slowing of product and product-related services revenue generation beginning in March 2020 as a result of the COVID-19 pandemic. This period of reduced revenue continued through the remainder of 2020 and continuing into 2021 due to disruptions to our customers' businesses as a result of the pandemic. The extent of this impact on our ongoing business is likely to vary from customer to customer depending upon how they are directly or indirectly impacted by local stay-at-home orders and other social distancing measures, priorities for the customers when the immediate impacts of the pandemic have passed, and the workforce and supplier impacts that each customer has experienced during the pandemic. Fluctuations in our operating results may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Factors that may contribute to fluctuations in our operating results include many of the risks described under the caption "Risk Factors – Risks Related to Our Business and Strategy" of this report. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. Our products involve a significant capital commitment from our customers or may depend on customer studies that have variable or indefinite timelines and accordingly, involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on our past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected.

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

Our sales process involves numerous interactions with multiple individuals within any given organization, and often includes in-depth analysis by potential customers of our products (where in some instances we will provide a demonstration unit for their use and evaluation), performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors, the capital investment required in purchasing our 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. Our collaborative development services revenue is also likely to be impacted by the ongoing COVID-19 pandemic.

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 revenue 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 types of our products (i.e. IVDs). 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 future success is dependent upon our ability to expand our customer base and introduce new applications.

Our current customer base is primarily composed of biopharmaceutical companies, academic institutions and molecular labs that perform analyses using or directly or indirectly obtain services based on our HTG EdgeSeq platform and consumables for research use only, which means that the products or data from services may not be used for clinical diagnostic purposes. We have obtained CE markings in Europe for our HTG EdgeSeq consumables, including our HTG EdgeSeq DLBCL Cell of Origin Assay EU and our HTG EdgeSeq ALK*Plus* Assay EU. These products may 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). 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, enter into service and collaborative development services arrangements with biopharmaceutical company customers, 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 platform 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 instruments 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.

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

We have initiated early development of a comprehensive transcriptome assay, which we are building for eventual clinical use and which we believe will serve as our anchor product not only for RUO profiling but also for our planned proprietary diagnostic products. In addition, we believe this product will serve as a universal CDx platform for gene expression profiling for our biopharmaceutical company customers. Moreover, we believe this product will allow us to expand our product offerings outside of oncology and autoimmune into markets such as transplant and diabetes. We cannot guarantee that we will be able to successfully develop a comprehensive transcriptome assay or that it will have the benefits that we anticipate. If we are unsuccessful at developing this assay or it does not provide the benefits that we anticipate, we may be limited in the breadth of additional products we can offer in the future, which could impact our future revenue and profits.

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 technology 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, including fees charged by our development partners to access new technology, 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.

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 platform 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 regulatory limitations are placed on our products our business and growth will be harmed.

In many jurisdictions, including the United States, we are currently limited to marketing our HTG EdgeSeq platform 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 obtained the right to CE mark the HTG EdgeSeq DLBCL Cell of Origin Assay EU and the HTG EdgeSeq ALK*Plus* Assay EU for sale as IVDs in Europe, in July 2016 and March 2017, respectively. If we are unable to maintain CE marking or achieve appropriate ex-U.S. approvals on any of our products for their intended commercial uses on a timely basis or at all, or if clinical

diagnostic laboratories or other customers outside the United States do not accept our tests, our ability to grow our business outside of the United States could be compromised.

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

Our clinical diagnostic business prospects in the United States and other applicable jurisdictions will depend on our ability to successfully complete clinical studies for product candidates that we intend to market as IVD kits. A failure of one or more clinical studies can occur at any stage of testing. The outcome of non-clinical studies may not be predictive of the success of clinical studies, and interim results, if any, of a clinical study do not necessarily predict final results. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in non-clinical and clinical studies have nonetheless failed to obtain premarketing 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 (“CRO’s”);
- different interpretations of our non-clinical and clinical data, which could initially lead to inconclusive results;
- delays in obtaining suitable patient samples for use in a clinical study; and
- delays on patient enrollment due to the COVID-19 pandemic.

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.

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

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 may now choose to develop companion diagnostic products independently or with a collaboration 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.

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 year ended December 31, 2020, approximately 35% of our revenue was generated from sales originated by customers located outside of the United States, compared with 34% for year ended December 31, 2019. We expect that a percentage of our future revenue will continue to come from international sources, and we expect to expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;

- export and import restrictions;
- various reimbursement, pricing and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers, including transfer pricing, value added and other tax systems, double taxation and restrictions and/or taxation on repatriation of earnings;
- tariffs, customs charges, bureaucratic requirements and other trade barriers;
- difficulties and costs of staffing and managing foreign operations, including difficulties and costs associated with foreign employment laws;
- increased financial accounting and reporting burdens and complexities; and
- difficulties protecting, procuring, or enforcing intellectual property rights, including from reduced or varied protection for intellectual property rights in some countries.

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

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

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

If the utility of our HTG EdgeSeq platform, 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 platform, 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 technology, 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 instrument 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 instrument 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 price over the term of the agreement. While some of these agreements did not historically contain a minimum purchase requirement, we have included a minimum purchase requirement in all 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 instrument 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 revenue and profit and potentially harm our long-term goal of achieving profitable operations. In addition, we require customers who receive systems that 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 instruments 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.

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.

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 certified 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.

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 instrument 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 revenue 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 produce a subcomponent used in our HTG EdgeSeq instruments. 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 instruments, 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 instruments, 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 platform.

We began manufacturing our HTG EdgeSeq platform 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 platform, entail unplanned additional costs and materially harm our business, results of operations and financial condition.

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.

Payments under the instruments governing our indebtedness may reduce our working capital. In addition, a default under our SVB Term Loan or cross default under our PPP Loan could cause a material adverse effect on our financial position.

Pursuant to the terms of the NuvoGen obligation, we have paid NuvoGen $10.1 million, and are required 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. Payments to NuvoGen will result in a reduction in our working capital as we continue to make payments on this obligation.

The SVB Term Loan 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; 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 SVB Term Loan, the lender could proceed against the collateral granted to them to secure our indebtedness or declare all obligation under the SVB 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. Our intellectual property is not included in the collateral granted to the lender but is subject to a negative pledge. 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.

Pursuant to the terms of our PPP Loan, we are required to make 8 equal monthly payments of principal and interest of any amounts that are not forgiven. All or a portion of the PPP Loan may be forgiven by the SBA upon its acceptance of our application and documentation of expenditures in accordance with the SBA requirements. Under the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) and PPP Flexibility Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments and covered utilities during the 24-week period beginning on the date of loan approval at the borrower’s option. Not more than 40% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven will be reduced if our full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25% during the measurement period, unless certain safe harbors are met. We will be required to repay any portion of the outstanding principal and interest that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

In order to apply for the PPP Loan, we were required to certify that, among other things, the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. In addition, PPP loans under the CARES Act may be subject to certain rules, regulations and Standard Operating Procedures ("SOPs") applicable to the SBA's Section 7(a) Loan Program, which includes PPP loans under the CARES Act. The interpretation and applicability of these rules, regulations and SOPs is unclear, as some of them have not been referenced in the CARES Act itself or in the guidance and interpretations issued by the SBA to date. If, despite our good-faith belief that we satisfied all eligible requirements for the PPP Loan, we are found to be in violation of any of the laws or governmental regulations that apply to us in connection with the PPP Loan, including the False Claims Act, or it is otherwise determined that we were not eligible to receive the PPP Loan, or it is determined that we have not adequately complied with the rules, regulations and SOPs applicable to the SBA's Section 7(a) Loan Program, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan in its entirety, which would have an impact on our liquidity. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

Changes in laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain tax provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, we had federal net operating loss carryforwards ("NOLs") to offset future taxable income of $177.6 million, of which $121.8 million will begin to expire after 2021 if not utilized, while the remainder can be carried forward indefinitely. A lack of future taxable income would adversely affect our ability to utilize these NOLs. Under the Tax Act, as modified by the CARES Act, our federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely but the deductibility of these federal NOLs is limited to 80% of taxable income, unless utilized in 2018, 2019, or 2020, in which case use of the NOLs is not limited. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), and corresponding provisions of state law, 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 pre-ownership change NOL carryforwards and certain other pre-ownership change tax attributes to offset post-ownership change income or taxes. 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 NOL carryforwards and other pre-ownership change tax attributes to offset post-ownership change income or taxes may be limited. Such limitations may cause a portion of our NOL and credit carryforwards to expire before we are able to utilize them. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. 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 platform 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. Following the U.S. Supreme Court decision in South Dakota v. Wayfair, Inc., states are now free to levy taxes on sales of goods and services based on an "economic nexus," regardless of whether the seller has a physical presence in the state. 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 instrument 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 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 or diagnostic products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, 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.

The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period that ended December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact on the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, and a separate marketing authorization will be required to marker our product candidates in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency, or MHRA, in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the UK and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the UK diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

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

Our business requires collecting, processing, manipulating, analyzing, disclosing and storing large amounts of proprietary, confidential and sensitive data, including personal information about our employees and others, information we collect from samples we process, intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other third parties. In addition, we rely on enterprise software systems and third-party service providers and sub-processors to operate and manage our business. The confidentiality, availability, integrity and protection of our data is critical to our business and relevant stakeholders have a high expectation that we will adequately protect confidential and sensitive data, including personal data. We also maintain personally identifiable information. Our business therefore depends on the continuous, effective, reliable and secure operation of our data, computer hardware, software, networks, internet servers and related infrastructure including those of our collaborators, service providers and contractors. To the extent that our hardware and software malfunction or access to our data is interrupted or otherwise compromised, our business could suffer. If we, our service providers, partners or other relevant third parties have experienced or in the future experience any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure of sensitive information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, indemnity obligations, negative publicity and financial loss. Further, failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations, including preventing us from conducting tests or research and development activities and preventing us from managing the administrative aspects of our business.

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 we have implemented physical, technical and administrative safeguards designed to protect our data, information technology systems and communications software, we are still vulnerable to natural or man-made hazards, such as natural disasters, fire, storm, flood, power loss, wind damage, terrorism, war, telecommunications failures, physical or software break-ins, inadvertent acts, malicious intrusion, malware, data leakage, viruses and similar events. Moreover, we are vulnerable to cyberattacks, malicious internet-based activity and online and offline fraud, which are prevalent and continue to increase. In addition to traditional computer "hackers," threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). We may also be the subject of phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data and other computer assets, adware or other similar issues. These events may result in damage to or the impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal data. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations. We could be required to expend significant resources, fundamentally change our business activities and practices or modify our services, software, operations or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual and potential vulnerabilities and security incidents. There can be no assurances that our security measures or those of our service providers, partners, and other third parties will be effective in protecting against all security breaches and the material adverse impacts that may arise from such breaches.

We have experienced specific instances of cyber events, including attempted compromises, in the past, and there could be unauthorized access, acquisition, disclosure and use of non-public information (including personal data) in the future. The techniques used to attack information technology systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we or relevant third parties on which we rely may not be able to address these techniques proactively or implement adequate preventative measures. If our data or information technology systems (or those of third parties upon which we rely) are compromised, we could be subject to reputational damage, fines, penalties, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. In addition, such a compromise may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to contract or various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. Such disclosures are costly, and the disclosures or the failure to comply with such requirements, could lead to material adverse impacts, including without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security or security breaches.

We are subject to stringent and changing privacy and data security laws, contractual obligations, self-regulatory schemes, government regulation, and standards related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with U.S. and foreign privacy and data protection laws, regulations and standards, external and internal privacy and security policies and representations, and other privacy and data-security related obligations may adversely affect our reputation, legal liability, business, operations and financial performance.

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, processing and security of personal data, such as information that we collect about employees and patients in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. We are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications, frameworks, and contractual obligations related to our collection, processing, use and disclosure of personal data and/or other confidential information. Although we endeavor to comply with our published policies and other obligations, and take steps to ensure that our external and internal privacy and security policies and representations are not inaccurate, incomplete, deceptive, unfair, or misrepresentative of our actual practices, we may at times fail to do so or may be perceived to have failed to do so. Compliance with these and any other applicable privacy and data security laws, regulations and obligations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms, potentially at significant expense, to ensure compliance with the new data protection rules. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures, representations or our contracts governing processing, of personal data could result in negative publicity, disruptions or interruptions in our operations, fines, penalties (including changes to our data practices), lawsuits, liability, an inability to process personal data, diversion of management time and effort and proceedings against us by governmental entities or others, all of which could adversely affect our business,

financial condition, results of operations and growth prospects. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, California adopted the California Consumer Privacy Act ("CCPA"), which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data. As we expand our operations, the CCPA may increase our compliance costs and potential liability. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. Other states have proposed similar laws and the landscape remains uncertain.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers and contractors must comply. For example, the EU has adopted the General Data Protection Regulation (EU) 2016/679 ("GDPR"), which went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals in the EU. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as health information, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Further, the UK's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to the regulation of data protection in the UK, including with respect to whether laws or regulations will apply to us consistent with the GDPR in the future and how data transfers to and from the UK will be regulated.

European data protection laws, including the GDPR, generally restrict the transfer of personal data from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards allowing U.S. companies to import personal data from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the European Union recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or most other countries. The European Commission recently proposed updates to the SCCs, and additional regulatory guidance has been released that seeks to impose additional obligations on companies seeking to rely on the SCCs. However, at present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers from Europe to the United States and the United Kingdom, whose data protection laws are similar to those of the European Union, may similarly invalidate use of the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield, respectively, as mechanisms for lawful personal data transfers from those countries to the United States. As such, if we are unable to rely valid data transfer solution for personal data transfers for Europe, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against processing personal data from Europe. Inability to import personal data from the European Economic Area, United Kingdom or Switzerland may also restrict our activities in Europe; limit our ability to collaborate with service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating 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 or approval 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 PMA and 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, and nine to 18 months for a PMA; however, it may take longer and 510(k) clearance or PMA approval may never be obtained. Even if the FDA accepts a 510(k) or PMA submission for filing, the FDA may request additional information or clinical studies during its review. Our ability to obtain additional regulatory clearances or approvals for new products and indications may be significantly delayed or may never be obtained. 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 revenue, 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 instrument and related proprietary panels. Accordingly, we expect to rely on third parties, such as medical institutions, CRO's 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 platform 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 genomic sequencing procedures ("GSPs"), including our diagnostic products, if approved. Effective January 1, 2015, these codes allow for uniform reporting of broad genomic testing panels using technology similar to ours. While these codes 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, Centers for Medicare and Medicaid Services ("CMS") issued preliminary determinations for 29 new molecular pathology codes, including the GSPs, of gapfill rather than cross-walking as recommended by the Association for Molecular Pathology. This means that local private Medicare Administrative Contractors, 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.

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.
- The Federal Health Insurance Portability and Accountability Act of 1996 ("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 the Health Information Technology for Economic and Clinical Health Act of 2009 ("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 and their contractors that perform services for them that involve the use, maintenance, or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information.
- The Federal Physician Payments Sunshine Act, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians, defined to include physicians, dentists, optometrists, podiatrists and chiropractors, 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, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives during the previous year.
- 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 altered the current payment methodology under the Medicare Clinical Laboratory Fee Schedule ("CLFS"). Effective January 1, 2018, the CLFS is based on weighted median private payor rates as required by PAMA. Under the law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), applicable clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes. The most recent data collection period was from January 1 through June 30, 2019, followed by a six-month validation period from July 1, 2019 through December 31, 2019. Thereafter, applicable laboratories will report their data. 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). In January 2020, CMS announced that data reporting for clinical diagnostic laboratory tests is delayed by one year. Moreover, the CARES Act, enacted in March 2020, further delays the reporting period by an additional year. Therefore, data that was originally required to be reported between January 1, 2020 and March 31, 2020 must now be reported between January 1, 2022 and March 31, 2022. Covered laboratories must report data from the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests will then resume on a three-year cycle beginning in 2025. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under

the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our products in development. In addition, CMS updated the statutory phase-in provisions such that, for 2020, the rates for clinical diagnostic laboratory tests may not be reduced by more than 10% of the rates for 2019. Pursuant to the CARES Act, the statutory phase-in of payment reductions has been extended through 2024, with a 0% reduction cap for 2021, and a 15% reduction cap for each of 2022, 2023, and 2024.

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. We cannot determine at this time the full impact of the law, including its implementing regulations, on our business, financial condition and results of operations.

The ACA made changes that significantly impacted 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. 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 remain judicial and Congressional challenges to certain aspects of the ACA. Then-President Trump signed several 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. 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 that repealed, 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”. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated medical device tax and “Cadillac” tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminated the health insurer tax. 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear when the Supreme Court will make a decision. It is also unclear how the Supreme Court ruling, other litigation and the healthcare reform measures of the Biden administration will impact the ACA and 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 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation, including the CARES Act, has suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021 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. 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 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 platform. 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 do 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

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 a “non-accelerated filer” 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. 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 a “smaller reporting company” and a “non-accelerated filer” and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to smaller reporting companies or non-accelerated filers could make our common stock less attractive to investors.

We are a “smaller reporting company” and a “non-accelerated filer” as defined in the Exchange Act, and for as long as we continue to be a “smaller reporting company” or a “non-accelerated filer,” we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “smaller reporting companies” or “non-accelerated filers,” 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 a “non-accelerated filer”) and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements (for so long as we are a “smaller reporting company”). We expect to be both a “smaller reporting company” and a “non-accelerated filer” in 2021. 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;

- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- 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. The ongoing COVID-19 pandemic, for example, has resulted in significant volatility in the stock market over the last several months. 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 2020 Equity Incentive Plan (“2020 Plan”) our Board of Directors is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. 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 13,000 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 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.

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.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our directors or officers or other employees arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate or our amended and restated bylaws; and/or (4) any action asserting a claim against us or any of our directors or officers or other employees governed by the internal affairs doctrine. The foregoing provisions do not apply to actions brought to enforce a duty or liability created by the Securities Act or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision in our governing documents to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate facilities are comprised of 37,100 square feet of administrative, laboratory and manufacturing spaces located in Tucson, Arizona. We occupy these facilities pursuant to two separate leases. Following its amendment in January 2019, which amended the lease to add approximately 7,000 square feet of additional administrative, manufacturing and laboratory space effective August 2019, the first lease concerns 24,500 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 first amended these leases in August 2015 to, among other things, align and extend the lease terms to expire in January 2021. Upon amendment of the first lease in 2019, the lease for the additional space was aligned to this January 2021 expiration. In December 2020, the leases were again amended to extend their terms for one additional year, through January 2022. The lease extension allows for an additional extension of three years upon the same terms and conditions of the existing amended lease agreements, except that lease rates would be adjusted to rates applicable to like-kind buildings within the market at the time we elect to exercise the extension option, but in no event to less than the last applicable rental rate. Base rent payable is currently approximately $21,000 per month and $16,000 per month, respectively, under the first and second leases, in each case for the remaining terms of the respective leases.

We also lease 4,800 square feet of administrative and development laboratory space in San Carlos, California, which we took occupancy on in April 2019. The initial term of this lease is 48 months, to expire in March 2023, with the option to extend the term for an additional 12 months. Base rent payable under this lease increases approximately 3% per year over the term of the lease from $21,600 per month in the first year to $23,616 per month in the final year of the lease, plus reimbursement of operating expenses to the landlord. Our landlord also holds a security deposit of $50,000 for this facility.

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 15, 2021, the last reported sale price of our common stock was $6.07 per share.

Holders

As of March 15, 2021, there were approximately 118 registered holders 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, the 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.

In November 2020, we completed a reverse stock split of our outstanding shares of common stock pursuant to which every fifteen (15) shares of issued and outstanding common stock were exchanged for one share of common stock. All share and per share amounts within Management's Discussion and Analysis of Financial Condition and Results of Operations has been adjusted to reflect the reverse stock split for all periods and dates presented.

Overview

We are a commercial stage RNA platform-based life sciences company focused on advancing the promise of precision medicine. Our product and service solutions are based on our proprietary next-generation HTG EdgeSeq technology that enables targeted RNA profiling using a small amount of biological sample, in liquid or solid forms. Our menu of HTG EdgeSeq assays is automated on our HTG EdgeSeq platform, which applies genomic sequencing tools that generate gene 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, including simplified bioinformatics. 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 HTG EdgeSeq technology can be used as a platform technology in clinical applications that will simplify, consolidate and reduce the cost of NGS-based diagnostic workflows and in commercialized CDx tests.

Our products include instruments, consumables, including assay kits, and software that, as an integrated platform, automate sample processing and can quickly, robustly and simultaneously profile tens, hundreds or thousands of molecular targets from samples a fraction of the size required by many prevailing technologies. Our objective is to establish our solutions as the standard in molecular profiling, companion diagnostic 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 the option to analyze such information locally to minimize turnaround time and cost.

Our HTG EdgeSeq technology, which generates a molecular profiling library for gene expression profiling 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 complementary ways in advancing precision health. Biopharmaceutical companies and other translational research centers utilize our technology to discover and validate biomarkers to develop an understanding of the mechanism of action of disease and to characterize molecular subtypes 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 design and sample processing services provided by our Tucson-based VERI/O laboratory, allow customers the ability to more efficiently identify and validate biomarker signatures across their drug portfolios or patient cohorts. Our ISO 13485- 2016 certified quality system and diagnostic development teams, in partnership with biopharmaceutical company customers, develop, manufacture and support clinical trials with investigation use only assays for potential companion diagnostics. Although our initial focus has been oncology, we have diversified into other disease areas including immune response, transplant and diabetes. Using 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 believe RNA-based applications represent a large and growing market with significant, unmet needs where our HTG EdgeSeq platform has allowed us to demonstrate competitive advantages and can enable gene expression profiling growth to accelerate as we make NGS-based gene expression analysis easier and more sample sparing.

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 a particular drug, validate these biomarkers in clinical trials and partner to commercialize the validated CDx assay. Customers can access 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, investigational-use-only assays for clinical trials or companion diagnostic assays for approved drugs. Our product and service solutions have provided us with a number of early-stage biomarker discovery 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 the drug development lifecycle with the highest value in the form of a drug linked companion diagnostic as the ultimate objective.

Customer Adoption of HTG Technology

Today we believe the primary measures of adoption for our technology are the number of total active customers, the number of active programs in our biopharmaceutical company customer pipeline, the number of instruments actively producing revenue in our installed base and revenue growth relating to new and existing customers.

Our ability to increase instrument and consumable revenue depends on several factors, including (i) adoption of our HTG EdgeSeq platform by our expanding 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 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 the sales cycle we have experienced historically, we expect fluctuations in our instrument and consumables sales on a period-to-period basis.

In the future, we expect to grow our active installed base and drive larger consumable annuities as we add new proprietary panels to our product menu, add to the utility of existing panels by expanding applications on our HTG EdgeSeq Reveal software and as European customers implement our existing or custom assays for use in clinical diagnostic testing as LDT’s under CLIA regulations. We remain focused on high quality instrument placements and consumable pull through at 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 and timing of biopharmaceutical company drug development processes and the development 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, all of which are expensed to research and development expense in our consolidated statements of operations, can 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.

2020 Highlights and Recent Developments

The full impact of the COVID-19 pandemic on our financial condition, liquidity and future results of operations remains fluid and uncertain as of the date of this report. We have experienced a significant slowing of product and product-related services revenue generation since March 2020 and we believe this period of reduced revenue will continue through at least the first half of 2021 due to continued disruptions to our customers' businesses from the pandemic and, in many instances, their prioritization of projects in areas focus related to COVID-19. We have also experienced limited delays in our development efforts as a result of stay-at-home orders and our efforts to prioritize the safety of our employees during this pandemic. However, all 2020 key development milestones were met and high priority development efforts continued, including extensive experiment study planning and analysis, despite the numerous operational challenges we have faced. We believe the COVID-19 pandemic will continue to impact our productivity, supply chains, distribution networks and other areas of our operation as the pandemic continues to disrupt our business and the businesses of our vendors, partners and customers.

Our 2020 development efforts were aimed at expansion of our capabilities in translational medicine with our RUO molecular profiling products, including adding to the utility of our targeted oncology, immuno-oncology, autoimmune and microRNA panels with the addition of new applications and analytical capabilities released in our HTG EdgeSeq Reveal software. This web-based biostatistical analysis software is designed to accelerate customer research by streamlining their statistical analysis of samples processed with our HTG EdgeSeq RUO profiling assays. In addition, we continued to reach key milestones in the development of our transcriptome product toward a planned initial RUO launch in the third quarter of 2021. This panel is expected to measure approximately 20,000 biomarkers and we believe that it will be a foundational product not only for RUO profiling, but also for potential companion diagnostic and proprietary diagnostic products. We also expect this product to expedite the expansion of our product offerings outside of oncology and autoimmune and into additional markets such as organ transplant and diabetes.

We announced an Early Adopter Program for our planned transcriptome product in December 2020 and expect to expand this program as we near the initial product launch. An initial white paper demonstrating technical feasibility for the product was produced in October 2020 and a second white paper demonstrating concordance to RNASeq and outlining the key elements of the product's expected value proposition was produced in February 2021.

Financial Operations Overview and Consolidated Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

	Years Ended December 31,		Change	
	2020	2019	$	%
Revenue:				
Product and product-related services	$ 7,890,854	$ 14,632,204	$ (6,741,350)	(46%)
Collaborative development services	658,010	4,571,684	(3,913,674)	(86%)
Total revenue	8,548,864	19,203,888	(10,655,024)	(55%)
Operating expenses:				
Cost of product and product-related services revenue	3,991,532	8,911,372	(4,919,840)	(55%)
Selling, general and administrative	18,063,064	18,682,396	(619,332)	(3%)
Research and development	6,079,907	10,570,225	(4,490,318)	(42%)
Total operating expenses	28,134,503	38,163,993	(10,029,490)	(26%)
Operating loss	(19,585,639)	(18,960,105)	(625,534)	3%
Loss on extinguishment of MidCap Credit Facility and QNAH Convertible Note	(522,394)	—	(522,394)	(100%)
Other income (expense)	(747,770)	(334,180)	(413,590)	124%
Net loss before income taxes	$ (20,855,803)	$ (19,294,285)	$ (1,561,518)	8%

Total Revenue

We have two primary sources of revenue: product and product-related services revenue from the sale of RUO and CE/IVD marked profiling products, sample processing services and custom assay design services to biopharmaceutical companies, academic research centers and molecular testing laboratories; and revenue from collaborative development services for companion diagnostic development programs for biopharmaceutical companies.

Profiling product and product-related services revenue includes customer purchases of our HTG EdgeSeq instrument and related assay kits, design of custom RUO assay kits for customers and the use of our HTG EdgeSeq instrument to process samples on the customer's behalf in our VERI/O laboratory. Customers can purchase our HTG EdgeSeq instrument and associated RUO and C/IVD

marked assays from a diverse portfolio of targeted RNA gene expression profiling panels based on our proprietary chemistry. This category of customer revenue includes sample processing services performed for additional customers by one of our certified service providers or Preferred Academic Centers of Excellence partners. Customers can also access our technology through contracted sample processing services performed by 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 consumable product revenue.

Collaborative development revenue relates to services performed using our HTG EdgeSeq proprietary technology to develop, seek regulatory approval for and commercialize companion diagnostic assays for biopharmaceutical drug candidates and corresponding therapeutics. Collaborative development services revenue recognized to date has been generated primarily pursuant to the Master Assay Development, Commercialization and Manufacturing Agreement between us and QIAGEN Manchester Limited ("QML") dated November 2016 (the "Governing Agreement"). In November 2019, we terminated the Governing Agreement. Our termination of the Governing Agreement did not terminate active statements of work under the Governing Agreement. On a going-forward basis, we expect to enter into additional collaborative development services arrangements directly with biopharmaceutical company customers, which we believe will result in improved economics from these arrangements and not limit the sequencing platform that must be used for development. In August 2020, we entered into a Commercialization and Distribution Agreement with QML that we believe will provide our customers distribution and commercialization options with QML in the event that a companion diagnostic assay is developed under one of these development services arrangements in the future.

Collaborative development services and product-related services revenue are generated through a service-oriented model. However, we anticipate that these services will be a catalyst toward a product-based strategy as an increase in our menu of proprietary panels is expected to continue to result in increased demand for our instrument and consumables products in individual laboratories and customer locations.

Total revenue decreased by 55% to $8.5 million for the year ended December 31, 2020 compared with total revenue of $19.2 million for the year ended December 31, 2019. The COVID-19 pandemic negatively impacted our ability to generate direct and collaborative development services revenue since March 2020 as numerous academic and biopharmaceutical company customers' facilities have been closed or partially closed due to the pandemic. These closures have limited our ability to ship instruments and consumables to customer facilities and have limited their ability to prepare and ship samples to our VERI/O laboratory. In addition, our customers have experienced significant delays in ongoing and planned clinical trials due to the demands the pandemic has placed on hospitals and clinicians.

In some geographies, especially at our global academic medical center customers' sites, we saw a growing number of these operations returning to work, at least on a limited capacity, in the second half of 2020. In other areas, such as our large biopharmaceutical customers, the reopening process was slower, especially on the east and west coasts of the United States where the rates of COVID-19 infection were highest and where closures for additional waves of infection continued throughout the year. In addition, many of these customers have continued operating with limited resources and have prioritized COVID-related programs, impacting our ability to resume non-COVID-related studies planned with these customers prior to the pandemic.

While we cannot be certain of the ultimate impact the COVID-19 pandemic will have on our business and that of our customers, we anticipate the generation of our product and product-related services revenue will resume in future periods as our and our customers' operations are able to return to pre-COVID-19 levels. Though we continue to seek potential, new customer collaborations, in which we would contract directly with customers, we do not anticipate additional revenue from our existing collaborative development services programs at this time and did not enter into any new collaborative development services agreements in 2020.

Product and product-related services revenue

Product and product-related services revenue, which includes revenue generated through the sale of our HTG EdgeSeq instruments and consumables and from services performed for customers using our proprietary RUO technology, decreased $6.7 million to $7.9 million for the year ended December 31, 2020 compared with $14.6 million for the year ended December 31, 2019, and was comprised of the following:

	Years Ended December 31,		Change	
	2020	2019	$	%
Product revenue:				
Instruments	$ 869,035	$ 1,436,730	$ (567,695)	(40%)
Consumables	3,030,612	3,010,094	20,518	1%
Total product revenue	$ 3,899,647	$ 4,446,824	$ (547,177)	(12%)
Product-related services revenue:				
Custom RUO assay design	1,393,316	4,498,088	(3,104,772)	(69%)
RUO sample processing	2,597,891	5,687,292	(3,089,401)	(54%)
Total product-related services revenue	3,991,207	10,185,380	(6,194,173)	(61%)
Total product and product-related services revenue	$ 7,890,854	$ 14,632,204	$ (6,741,350)	(46%)

Product revenue generated from the sale of our HTG EdgeSeq instruments and RUO and CE/IVD marked assay kits decreased 12% to $3.9 million for the year ended December 31, 2020 compared with $4.4 million for the year ended December 31, 2019. This decrease in product revenue in 2020 compared with 2019 primarily reflects the impact of COVID-19 on our business and on our customers' businesses. Since March 2020, we experienced a limited ability to ship instruments and consumables to customers' facilities due to COVID-19-related shutdowns, and a slower than anticipated return to pre-COVID purchasing patterns in the later part of the year. Product revenue represented 46% and 23% of our total revenue for the years ended December 31, 2020 and 2019, respectively. The increase in product revenue as a percentage of total revenue reflects a growing European customer base, which has historically accessed our technology through instrument and consumables purchases rather than through our service business. European customers generally began their return to work in the second and third quarters of 2020 to a greater extent than our domestic customer base. We continue to discuss opportunities for future studies with both new and existing customers and expect demand for our products to continue to increase as our customers are able to return to pre-COVID operating levels.

Product-related services revenue, consisting of sample processing using HTG EdgeSeq instruments and consumables in our VERI/O laboratory and custom RUO assay development services, decreased $6.2 million to $4.0 million for the year ended December 31, 2020 compared with $10.2 million for the year ended December 31, 2019. The decrease in service revenue for the year ended December 31, 2020 compared with 2019 primarily reflects a reduction in RUO sample processing services revenue due to COVID-19-related cancellations or delays in sample receipt for anticipated customer programs and planned customer study reprioritization. This decrease also reflects high levels of subcontracted laboratory services in 2019 which did not recur in 2020. Product-related services revenue represented 47% and 53% of our total revenue for the years ended December 31, 2020 and 2019, respectively. Although a number of our customers began to return to pre-COVID-19 operating levels during the second half of 2020, our larger biopharmaceutical company customers, who have historically represented the largest portion of our services business, have generally been slower to resume onsite operations or reprioritized current year projects due to COVID-19 impacts on their overall operations. It remains uncertain if our larger biopharmaceutical customers will resume previously planned studies in the future as their activities return to pre-COVID levels.

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. To date, collaborative development services revenue has reflected revenue generated from precision diagnostic program services performed for biopharmaceutical companies pursuant to our Governing Agreement with QML. Collaborative development services revenue decreased $3.9 million to $0.7 million for the year ended December 31, 2020 compared with $4.6 million for the year ended December 31, 2019 and represented 8% and 24% of our total revenue for the years ended December 31, 2020 and 2019, respectively. Collaborative development services revenue for the year ended December 31, 2020 included $0.5 million of monthly development fees and $0.2 million of profit-sharing payments. Collaborative development services revenue for the year ended December 31, 2019 included $3.2 million of monthly development fees and $1.4 million of profit-sharing payments. These decreases reflect the completion of remaining contracted development tasks on our existing programs. No additional collaborative development services programs were entered into during 2020. Though we continue to seek potential, new customer collaborations, we do not anticipate additional revenue from our existing collaborative development services programs at this time.

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 consumables and lab supplies, 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. Due to the fixed nature of certain of these 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 our product and product-related services revenue increases, further absorbing these fixed costs.

Cost of product and product-related services revenue decreased by 55% to $4.0 million for the year ended December 31, 2020 compared with $8.9 million for the year ended December 31, 2019. This overall decrease reflects the decrease in product and product-related services revenue in 2020 compared with 2019.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of personnel costs for our sales and marketing, regulatory, legal, executive management, 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 decreased by 3% to $18.1 million for the year ended December 31, 2020 compared with $18.7 million for the year ended December 31, 2019. This decrease primarily reflects a decrease in tradeshow attendance and travel expenses, due to travel restrictions and curtailment of in-person tradeshow activities in 2020 as a result of the COVID-19 pandemic. In addition, costs incurred to conduct a strategic market study did not recur in 2020.

Research and development expenses

Research and development expenses represent amounts incurred to perform collaborative development services, costs to develop new proprietary panels and costs to continue to develop and improve upon our HTG EdgeSeq technology. These expenses include payroll and related expenses, consulting fees, laboratory supplies, facilities and equipment. Research and development costs are expensed as incurred. Research and development expenses decreased by 42% to $6.1 million for the year ended December 31, 2020 compared with $10.6 million for the year ended December 31, 2019. This decrease is related to a reduction in collaborative development services costs, which are included in research and development expense in our consolidated statements of operations, and a related decrease in research and development headcount from 2019 to 2020 in response to this reduced collaborative development services demand. Research and development costs relating to our collaborative development services revenue were $0.5 million for the year ended December 31, 2020 compared with $2.8 million for the year ended December 31, 2019.

Interest income (expense)

As of December 31, 2020, we had an obligation due to NuvoGen in the amount of $5.0 million under an asset purchase agreement and a SVB Term Loan obligation of $9.7 million, net of discount and deferred financing costs. As of December 31, 2019, in addition to our obligation to NuvoGen, we had an obligation of $6.9 million under the MidCap Credit Facility and $3.0 million under the QNAH Convertible Note. Interest expense and non-cash interest expense recognized for discount, deferred financing fee amortization and final fee premium amounts relating to these obligations was $1.0 million for both the years ended December 31, 2019 and 2020. Interest income related to our available-for-sale debt securities investments included in interest income (expense) decreased by 59% to $0.3 million for the year ended December 31, 2020 as compared with $0.6 million for the year ended December 31, 2019 due to the market impacts of the COVID-19 pandemic.

Cash Flows for the Years Ended December 31, 2020 and 2019

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

	Years Ended December 31,		Change	
	2020	2019	$	%
Net cash provided by (used in):				
Operating activities	$ (16,292,377)	$ (16,695,936)	403,559	(2%)
Investing activities	18,731,107	(3,504,384)	22,235,491	(635%)
Financing activities	9,049,478	19,391,804	(10,342,326)	(53%)
Effect of exchange rate on cash	19,609	(4,336)	23,945	(552%)
Increase (decrease) in cash, cash equivalents and restricted cash	$ 11,507,817	$ (812,852)	12,320,669	(1516%)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 decreased by 2% to $16.3 million compared with $16.7 million for the year ended December 31, 2019. This decrease for the year ended December 31, 2020 reflected (i) the net loss of $20.9 million and (ii) net non-cash items of $4.7 million, consisting primarily of stock-based compensation of $1.6 million, depreciation and amortization of $1.3 million, non-cash operating lease expense of $0.6 million and loss on extinguishment of the Midcap Credit Facility and QNAH Convertible Note of $0.5 million.

Net cash used in operating activities for the year ended December 31, 2019 was $16.7 million and reflected (i) the net loss of $19.3 million and (ii) net non-cash items of $3.1 million, consisting primarily of stock-based compensation of $1.2 million and depreciation and amortization of $1.3 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2020 increased by 635% to $18.7 million compared with net cash used in investing activities of $3.5 million for the year ended December 31, 2019. Net cash provided by investing activities for the year ended December 31, 2020 consisted primarily of purchases of available-for-sale securities of $12.5 million, partially offset by the maturity of $31.7 million of the available-for-sale securities and the purchase of $0.5 million of laboratory equipment and other fixed assets during the year.

Net cash used in investing activities for the year ended December 31, 2019 was $3.5 million and consisted primarily of purchases of available-for-sale securities of $34.6 million, partially offset by the maturity of $32.2 million of the available-for-sale securities and the purchase of $1.1 million of laboratory equipment for our California-based technology center and other fixed assets during the year.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 decreased by 53% to $9.0 million compared with $19.4 million for the year ended December 31, 2019. This activity for the year ended December 31, 2020 consisted primarily of $7.5 million in net proceeds from our underwritten public and private offerings, $1.7 million in proceeds from our PPP Loan and $0.6 million in payments on our NuvoGen obligation.

Net cash provided by financing activities for the year ended December 31, 2019 was $19.4 million. This activity for the year ended December 31, 2019 consisted primarily of $20.8 million in net proceeds from our 2019 underwritten public and private offerings and $1.3 million in payments 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, 2020, we had $28.7 million in cash, cash equivalents and investments in short-term available-for-sale securities, and $20.7 million of liabilities outstanding primarily relating to our SVB Term Loan, NuvoGen and PPP Loan obligations and our financing and operating leases.

In September 2019, we completed an underwritten public offering in which we sold 1,953,235 shares of our common stock at a price of $9.75 per share, including 254,769 shares sold pursuant to the exercise in full of the underwriter's option to purchase additional shares. The shares of common stock described above were offered pursuant to a Registration Statement on Form S-3 (File No. 333-229045) previously filed with the SEC and declared effective by the SEC on February 11, 2019, and a prospectus supplement thereafter. In addition, we concurrently entered into a securities purchase agreement with certain institutional accredited investors for the sale of pre-funded warrants exercisable for an aggregate of 360,779 shares of our common stock, at a purchase price of $9.60 per pre-funded warrant. The aggregate net proceeds from these offerings for the year ended December 31, 2019 were $20.8 million, after deducting the underwriting discounts and commissions and offering expenses. Additional proceeds of $31,768 were received in the first quarter of 2020 as a result of the exercise of a portion of the pre-funded warrants for 211,784 shares of our common stock.

In November 2019, we entered into a Controlled Equity Offering Sales Agreement (the "Cantor Sales Agreement") with Cantor Fitzgerald and Co. ("Cantor") as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor, shares of our common stock by any method deemed to be an "at the market offering" as defined by rule 415(a)(4) under the Securities Act (the "ATM Offering"). The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-229045). We have offered and sold 955,240 shares of our common stock under the ATM Offering through December 31, 2020 for net proceeds of $7.5 million. As of December 31, 2020, we were permitted to sell up to $7.4 million worth of additional shares of our common stock under the current prospectus supplement for the ATM Offering of which we have sold $6.9 million from January 1 through March 15, 2021 for net proceeds of approximately $6.7 million after sales commissions.

In February 2020, we issued 41,100 shares of our Series A convertible preferred stock ("Series A Preferred") to accredited investors, in exchange for the investors surrendering to us for cancellation an aggregate of 274,000 shares of our common stock. In addition, we sold an aggregate of 10,170 additional shares of our Series A Preferred to the accredited investors for aggregate gross proceeds of $0.6 million, and transaction costs of approximately $37,000. Each share of Series A Preferred is convertible into 6.67 shares of our common stock, subject to proportional adjustment and beneficial ownership limitations. In June 2020, the investors elected to convert 27,500 shares of Series A Preferred to common stock, resulting in the issuance of 183,333 shares of the Company's common stock. The remaining 23,770 shares of Series A Preferred remain outstanding as of December 31, 2020. In the event of our liquidation, dissolution or winding up, holders of Series A Preferred will participate pari passu with any distribution of proceeds to holders of our common stock. Holders of Series A Preferred are entitled to receive dividends on shares of Series A Preferred equal (on an as converted to common stock basis) to and in the same form as dividends actually paid on our common stock. Shares of Series A Preferred generally have no voting rights, except as required by law.

In March 2020, we entered into a purchase agreement ("LP Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, we have the right to sell to Lincoln Park up to $20.0 million of shares of our common stock ("Purchase Shares") from time to time over the 36-month term of the LP Purchase Agreement. The purchase price of the Purchase Shares will be based on recent closing prices of our common stock at the time of sale. We issued Lincoln Park an aggregate of 41,026 shares of our common stock as consideration for their purchase commitment pursuant to the LP Purchase Agreement. As of December 31, 2020, 197,632 shares of our common stock have been sold to Lincoln Park under the LP Purchase Agreement.

In April 2020, we received the proceeds from the PPP Loan in the amount of $1,717,000 from SVB, as lender, pursuant to the Paycheck Protection Program of the CARES Act. The PPP Loan matures on April 21, 2022 and bears interest at an annual rate of 1%. We applied for full PPP Loan forgiveness in October 2020. However, there can be no assurance given that we will obtain forgiveness of the PPP Loan in whole or in part. Beginning in September 2021, we are required to make 8 equal monthly payments of principal and interest for all amounts that are not forgiven through the SBA's application and documentation process. We may prepay the PPP Loan at any time prior to maturity with no prepayment penalties.

On June 24, 2020, we entered into the Loan Agreement in the principal amount of $10.0 million with SVB. The proceeds from the SVB Term Loan were fully funded on the June 25, 2020. The proceeds from the SVB Term Loan, together with cash on hand, were used to repay in full all outstanding amounts and fees due under the MidCap Credit Facility and the QNAH Convertible Note. Our SVB Term Loan bears interest at a floating rate equal to the greater of 2.50% above the Prime Rate (as defined in the Loan Agreement) and 5.75% and requires interest-only payments payable monthly in arrears through June 30, 2021. This interest-only period may be extended for an additional six months upon achievement of an equity milestone defined in the Loan Agreement. The ultimate interest-only period will be followed by equal monthly payments of principal and interest through the maturity date of December 1, 2023. In addition, we must comply with a financial covenant requiring that we maintain a certain amount of unrestricted cash under the Loan Agreement (see Note 8 to our consolidated financial statements included elsewhere in this report). If sufficient additional capital is not available as and when needed, 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 a sale of the Company at a price that may result in a significant loss on investment for our stockholders, file for bankruptcy or seek other protection

from creditors, or liquidate all assets. In addition, if we default under the Loan Agreement, SVB could accelerate the payment of the SVB Term Loan and ultimately foreclose on our assets.

Funding Requirements

We have had recurring operating losses and negative cash flows from operations since our inception and have an accumulated deficit of $191.2 million as of December 31, 2020. As of December 31, 2020, we had cash, cash equivalents and investments in short-term available-for-sale securities of $28.7 million and had current liabilities of $7.2 million. As of December 31, 2020, we also had $13.5 million in long-term liabilities primarily attributable to our SVB Term Loan, PPP Loan, and NuvoGen obligations. While we believe that our existing resources will be sufficient to fund our planned operations and expenditures for at least the next 12 months from the issuance of these consolidated financial statements, potential changing circumstances, especially those related to the COVID-19 pandemic, may result in the depletion of our capital resources more rapidly than we currently anticipate, resulting in our inability to fund our planned operations and expenditures for at least the next 12 months. These circumstances raise substantial doubt about our ability to continue as a going concern.

Until our revenue reaches a level sufficient to support self-sustaining cash flows, if ever, we will need to raise additional capital to fund our continued operations, including our product development and commercialization activities related to our current and future products. Future funding requirements will depend on a number of factors, including our ability to generate significant 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 or are only able to raise insufficient amounts or funds 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 a significant loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets. In addition, if we default under the Loan Agreement, SVB could accelerate the payment of the SVB Term Loan and ultimately foreclose on 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

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 financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Items subject to estimates based on judgments include, but are not limited to: revenue recognition, stock-based compensation expense, the resolution of uncertain tax positions, income tax valuation allowances, recovery of long-lived assets, inventory obsolescence and valuation of inventory, accounts receivable and available-for-sale securities. Actual results could materially 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 our 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 shipped are included in the consolidated statements of operations as part of product and product-related services revenue. Shipping and handling costs for products shipped to customers are included in the 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. Standard delivery terms for sales to customers outside of the United States are FOB delivery point, unless otherwise specified in the customer contract. 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 our customers through our 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 with 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. For the years ended December 31, 2019 and 2018, collaborative development services revenue was generated from our Governing Agreement with QML. We have determined that the statements of work signed under the Governing Agreement 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.

Leases

We account for our leases under ASC 842, *Leases* (“ASC 842”). Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheets as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or our incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. For financing leases, interest on the lease liability and the amortization of the right-of-use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded to rent expense as incurred.

In calculating the right-of-use asset and lease liability, we have elected to combine lease and non-lease components for all classes of assets currently under lease, including facilities and computer equipment. We have also excluded short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term for these leases.

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.

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. Financial Statements and Supplementary Data.

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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") as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, 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 at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, negative operating cash flows, and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for the Common Stock Purchase Agreement

As described in Note 14 to the consolidated financial statements, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC, pursuant to which the Company has the right to sell up to $20.0 million of shares of its common stock from time to time over the 36-month term of the purchase agreement. For each sale of common stock during the period of the agreement, the purchase price will be established by a formula based on the recent closing prices of the Company's common stock leading up to the date of the sale. The Company determined that the right to sell shares under this agreement represents a freestanding put option.

We identified the accounting for the put option as a critical audit matter. The assessment of whether the instrument is indexed to the Company's own equity and classified as equity or an instrument that is a derivative asset and adjusted to fair value at each reporting period is complex and requires significant judgments in the application of the relevant accounting standards. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skillsets and knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Reviewing the purchase agreement and management's technical accounting memo to assess the (i) appropriateness of management's interpretation of the key terms of the agreement, and (ii) reasonableness of assumptions used by management to determine whether the instrument is indexed to the Company's own equity or an instrument that is a derivative asset.

- Utilizing personnel with specialized knowledge and skill in equity and derivative accounting to evaluate the appropriateness of management's application of the relevant accounting guidance for the purchase agreement.

/s/ BDO USA, LLP

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

Los Angeles, California
March 25, 2021

HTG Molecular Diagnostics, Inc.
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 22,397,812	$ 7,619,748
Short-term investments available-for-sale, at fair value	6,298,075	25,410,222
Restricted cash	—	3,270,247
Accounts receivable	1,588,767	3,164,176
Inventory, net of allowance of $26,052 at December 31, 2020 and $39,403 at December 31, 2019	1,492,126	1,269,667
Prepaid expenses and other	1,094,273	633,522
Total current assets	32,871,053	41,367,582
Operating lease right-of-use assets	1,009,097	1,209,145
Property and equipment, net	1,227,402	2,240,133
Other non-current assets	90,356	302,409
Total assets	$ 35,197,908	$ 45,119,269
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,348,762	$ 1,662,583
Accrued liabilities	1,459,878	1,870,296
Contract liabilities - current	185,083	426,014
NuvoGen obligation - current	512,729	1,152,233
Current portion of long-term debt, net	3,022,139	2,987,667
Operating lease liabilities - current	685,220	758,932
Other current liabilities	22,563	41,134
Total current liabilities	7,236,374	8,898,859
NuvoGen obligation - non-current, net of discount	4,479,396	4,498,777
Long-term debt, net of current portion and discount and debt issuance costs	8,568,308	6,871,545
Operating lease liabilities - non-current	368,682	636,340
Other non-current liabilities	60,488	244,114
Total liabilities	20,713,248	21,149,635
Commitments and Contingencies (Note 15)		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value; 23,770 shares authorized, issued and outstanding at December 31, 2020 and no shares authorized, issued or outstanding at December 31, 2019	24	—
Common stock, $0.001 par value; 26,666,667 shares authorized at December 31, 2020 and December 31, 2019, 5,199,997 shares issued and outstanding at December 31, 2020 and 3,872,682 shares issued and outstanding at December 31, 2019	5,200	3,873
Additional paid-in-capital	205,661,999	194,288,368
Accumulated other comprehensive income (loss)	5,298	(4,964)
Accumulated deficit	(191,187,861)	(170,317,643)
Total stockholders' equity	14,484,660	23,969,634
Total liabilities and stockholders' equity	$ 35,197,908	$ 45,119,269

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

HTG Molecular Diagnostics, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2020	2019
Revenue:		
Product and product-related services	$ 7,890,854	$ 14,632,204
Collaborative development services	658,010	4,571,684
Total revenue	8,548,864	19,203,888
Operating expenses:		
Cost of product and product-related services revenue	3,991,532	8,911,372
Selling, general and administrative	18,063,064	18,682,396
Research and development	6,079,907	10,570,225
Total operating expenses	28,134,503	38,163,993
Operating loss	(19,585,639)	(18,960,105)
Other income (expense):		
Interest expense	(1,024,774)	(957,535)
Interest income	254,736	623,355
Other income	22,268	—
Loss on extinguishment of MidCap Credit Facility and QNAH Convertible Note	(522,394)	—
Total other expense	(1,270,164)	(334,180)
Net loss before income taxes	(20,855,803)	(19,294,285)
Provision for income taxes	(14,415)	(3,379)
Net loss	$ (20,870,218)	$ (19,297,664)
Net loss per share, basic and diluted	$ (4.51)	$ (7.60)
Shares used in computing net loss per share, basic and diluted	4,627,918	2,539,979

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,	
	2020	2019
Net loss	$ (20,870,218)	$ (19,297,664)
Other comprehensive income (loss), net of tax effect:		
Unrealized gain on short-term investments	9	2,299
Foreign currency translation adjustment	10,253	(3,810)
Total other comprehensive income (loss)	10,262	(1,511)
Comprehensive loss	$ (20,859,956)	$ (19,299,175)

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

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

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at January 1, 2019	-	$ -	1,905,696	$ 1,906	$ 172,113,588	$ (3,453)	$ (151,019,979)	$ 21,092,062
Exercise of stock options	—	—	3,617	4	120,950	—	—	120,954
Stock-based compensation expense	—	—	—	—	1,156,486	—	—	1,156,486
Release of restricted stock awards	—	—	5,431	5	76	—	—	81
Net share settlement of restricted stock award	—	—	(1,128)	(1)	(30,903)	—	—	(30,904)
Stock issued under stock purchase plans	—	—	5,830	6	171,184	—	—	171,190
Issuance of common stock from underwritten public and private offerings, net of underwriting discounts, commissions and issuance costs of approximately $1.7 million	—	—	1,953,236	1,953	20,756,987	—	—	20,758,940
Net loss	—	—	—	—	—	—	(19,297,664)	(19,297,664)
Unrealized gain on short-term investments	—	—	—	—	—	2,299	—	2,299
Foreign currency translation adjustment	—	—	—	—	—	(3,810)	—	(3,810)
Balance at December 31, 2019	-	$ -	3,872,682	$ 3,873	$ 194,288,368	$ (4,964)	$ (170,317,643)	$ 23,969,634
Stock-based compensation expense	—	—	—	—	1,584,666	—	—	1,584,666
Release of restricted stock awards	—	—	7,911	8	111	—	—	119
Net share settlement of restricted stock award	—	—	(1,764)	(2)	(14,047)	—	—	(14,049)
Stock issued under stock purchase plans	—	—	6,286	6	62,156	—	—	62,162
Issuance of common stock from ATM offering, net of commissions and issuance costs of approximately $0.3 million	—	—	955,240	955	7,544,883	—	—	7,545,838
Issuance of Series A convertible preferred stock in private placement, net of issuance costs of approximately $37,000	10,170	10	—	—	562,945	—	—	562,955
Cancellation of common stock received in exchange for Series A convertible preferred stock	—	—	(274,000)	(274)	(2,424,626)	—	—	(2,424,900)
Issuance of Series A convertible preferred stock in exchange for outstanding common stock	41,100	41	—	—	2,424,859	—	—	2,424,900
Conversion of Series A convertible preferred stock for common stock	(27,500)	(27)	183,333	183	(156)	—	—	-
Shares issued, including stock compensation expense in connection with LP Purchase Agreement	—	—	238,658	239	1,181,844	—	—	1,182,083
Exercise of pre-funded warrants	—	—	211,784	212	31,556	—	—	31,768
Issuance of common stock warrants in connection with SVB Term Loan	—	—	—	—	420,000	—	—	420,000
Cash in lieu of fractional shares related to reverse stock split	—	—	(133)	—	(560)	—	—	(560)
Net loss	—	—	—	—	—	—	(20,870,218)	(20,870,218)
Unrealized gain on short-term investments	—	—	—	—	—	9	—	9
Foreign currency translation adjustment	—	—	—	—	—	10,253	—	10,253
Balance at December 31, 2020	23,770	$ 24	5,199,997	$ 5,200	$ 205,661,999	$ 5,298	(191,187,861)	$ 14,484,660

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,	
	2020	2019
Operating activities		
Net loss	$ (20,870,218)	$ (19,297,664)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,346,560	1,259,015
Accretion of discount on NuvoGen obligation	(12,936)	(13,821)
Provision for excess inventory	53,298	153,729
Write-off of Cowen ATM offering costs	—	108,883
Amortization of QNAH Convertible Note issuance costs	6,505	13,454
Amortization of MidCap Credit Facility discount and issuance costs	101,482	183,002
Amortization of SVB Term Loan discount and issuance costs	243,541	—
Stock-based compensation expense	1,584,785	1,156,567
Employee stock purchase plan expense	21,186	66,238
Non-cash operating lease expense	629,501	476,789
Accrued interest on available-for-sale securities investments	(72,503)	(325,666)
Stock compensation expense in connection with LP Purchase Agreement	205,538	—
Loss on extinguishment of Midcap Credit Facility and QNAH Convertible Note	522,394	—
Loss on abandonment and disposal of assets, net	105,063	9,051
Changes in operating assets and liabilities:		
Accounts receivable	1,575,409	1,848,502
Inventory	(256,940)	(116,787)
Prepaid expenses and other	284,921	(177,307)
Deferred offering costs	140,320	—
Accounts payable	(23,801)	(155,974)
Accrued liabilities	(409,035)	(1,440,065)
Contract liabilities	(683,716)	188,507
Operating lease liabilities	(783,731)	(632,389)
Net cash used in operating activities	(16,292,377)	(16,695,936)
Investing activities		
Purchase of property and equipment	(453,552)	(1,103,176)
Maturities of available-for-sale securities	31,650,000	32,200,000
Purchase of available-for-sale securities	(12,465,341)	(34,601,208)
Net cash provided by (used in) investing activities	18,731,107	(3,504,384)
Financing activities		
Proceeds from issuance of SVB Term Loan	10,000,000	—
Payment of SVB Term Loan issuance costs	(115,193)	—
Payments for extinguishment of MidCap Credit Facility	(7,438,623)	—
Payments for extinguishment of QNAH Convertible Note	(3,000,000)	—
Proceeds from 2019 underwritten public and private offerings, net of underwriting discounts, commissions and costs of $1.7 million	—	20,758,940
Proceeds from ATM Offering, net of commissions and costs of $0.3 million	7,545,838	—
Proceeds from LP Purchase Agreement	976,545	—
Proceeds from PPP Loan	1,717,000	—
Proceeds from Series A convertible preferred stock in private placement	562,955	—
Payments on NuvoGen obligation	(645,949)	(1,327,922)
Proceeds from exercise of pre-funded warrants	31,768	—
Payments on financing leases	(41,134)	(44,043)
Proceeds from exercise of stock options	—	120,954
Taxes paid for net share settlement of restricted stock awards	(14,049)	(30,904)
Cash in Lieu of fractional shares related to reverse stock split	(560)	—
Proceeds from shares purchased under stock purchase plans	40,976	104,952
Payment of deferred offering costs	—	(190,173)
Payments on Insurance Note	(570,096)	—
Net cash provided by financing activities	9,049,478	19,391,804
Effect of exchange rates on cash	19,609	(4,336)
Increase (decrease) in cash, cash equivalents and restricted cash	11,507,817	(812,852)
Cash, cash equivalents and restricted cash at beginning of year	10,889,995	11,702,847
Cash, cash equivalents and restricted cash at end of year	$ 22,397,812	$ 10,889,995
Supplemental disclosure of noncash investing and financing activities		
Issuance of Series A convertible preferred stock in exchange for outstanding common stock	$ 2,424,900	$ -
Issuance of common stock upon conversion of Series A convertible preferred stock	1,622,500	—
Issuance of common stock warrants in connection with SVB Term Loan	420,000	—
Fixed asset purchases payable and accrued at period end	—	8,299
Adoption of ASC 842, Leases	—	694,352
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	447,987	1,005,085
Financing lease right-of-use assets obtained in exchange for financing lease liabilities	—	63,406
Carrying value of demonstration units transferred from property and equipment to inventory	18,817	—
Reclassification of contract liability to refund liability	281,722	—
Insurance Note issued for insurance premiums	735,195	—
Supplemental cash flow information		
Cash paid for interest	$ 869,857	$ 686,042
Cash paid for taxes	17,514	3,379

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 instrument system and integrated next-generation sequencing-based ("NGS-based") HTG EdgeSeq assays, from services including sample processing and custom research use only ("RUO") assay design and from collaborative development services.

The Company operates in one segment and its customers are located primarily in the United States and Europe. For the year ended December 31, 2020, approximately 35% of the Company's revenue was generated from sales originated by customers located outside of the United States, compared with 34% for the year ended December 31, 2019.

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"). In November 2020, the Company completed a reverse stock split of its outstanding shares of common stock pursuant to which every fifteen shares of issued and outstanding common stock were exchanged for one share of common stock. All share and per share amounts within the consolidated financial statements and notes thereto have been adjusted to reflect the reverse stock split for all periods and dates presented. See Note 14 for more information about the Company's reverse stock split.

Principles of Consolidation

The Company formed a French subsidiary, HTG Molecular Diagnostics France SARL, 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, 2020 and 2019.

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.

COVID-19 Pandemic

The full impact of the COVID-19 pandemic continues to evolve as of the date of this report and management continues to actively monitor the potential impact of the global situation on its financial condition, liquidity, operations, suppliers, industry and workforce. Given the ongoing evolution of the COVID-19 pandemic, including resurgences in many areas of the world and the global responses to curb its spread, the Company is not able to fully estimate the effects of the COVID-19 pandemic on its results of operations, financial condition or liquidity.

The Company experienced a significant slowing of product and product-related services revenue generation beginning in March 2020 and believes that while it has seen some recovery in the later part of 2020, this impact will continue to be seen at some level at least through the first half of 2021. The extent of this impact varied from customer to customer depending upon how they have been directly or indirectly impacted by local stay-at-home orders and other social distancing measures, prioritization by those customers as the immediate impacts of the pandemic have passed, and the workforce and supplier impacts that each customer has experienced during the pandemic. The Company has experienced very limited delays in its development efforts because of stay-at-home orders despite its efforts to prioritize the safety of its employees during this pandemic. The Company believes the COVID-19 pandemic will continue to impact its productivity, supply chains, distribution networks and other areas of its operation as ongoing concerns regarding the pandemic continue to disrupt the Company's business and the businesses of its vendors, partners and customers and as shipping and manufacturing resources are prioritized throughout the world to fight the continued spread of the pandemic.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to the COVID-19 pandemic. On April 21, 2020, the Company received proceeds from a loan in the amount of $1.7 million from Silicon Valley Bank ("SVB"), as lender, pursuant to the Paycheck Protection Program ("PPP") of the CARES Act (the "PPP Loan") (see Note 8). The CARES Act also addressed a number of tax-related matters for consideration in preparation of the Company's 2020 income tax returns (see Note 16). The Company does not expect that these provisions will have a significant impact on its consolidated financial statements.

In December 2020, the Consolidated Appropriations Act (the "Appropriations Act") was signed into law to further address the ongoing impacts of the COVID-19 pandemic. The Appropriations Act introduced several additional potential credits and benefits for employers to consider including, but not limited to, the ability for employers who have previously obtained a PPP Loan to potentially also qualify for the Employee Retention Credit, initially created as part of the CARES Act. The Company expects to qualify for benefits available to it under the Appropriations Act for the year ended December 31, 2020 and will continue to seek out these benefits in future periods as appropriate.

While there remains uncertainty as to the ultimate impact of the COVID-19 pandemic, the Company has considered the known impacts on its business as of the date these consolidated financial statements were issued and has reflected any known or expected impacts in its consolidated financial statements, including consideration of potential impairment risks to its long-lived assets, potential accounts receivable collection risks and potential impacts to its overall liquidity position.

Going Concern and Liquidity

Management has assessed the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of the assets and satisfaction of liabilities in the normal course of business. However, the Company has had recurring operating losses and negative operating cash flows since its inception and has an accumulated deficit of $191.2 million as of December 31, 2020. As of December 31, 2020, the Company had working capital of $25.6 million and long-term liabilities of $13.5 million. The Company's liability balances consist primarily of its debt obligations, including an asset-secured Loan and Security Agreement (the "Loan Agreement") with SVB, the PPP Loan, and a commercial financing agreement extending the payment period related to its director and officer insurance policy (the "Insurance Note") (see Note 8), as well as an obligation to NuvoGen Research, LLC (the "NuvoGen obligation") (see Note 10). While the Company believes that its existing resources may be sufficient to fund its planned operations and expenditures for at least the next 12 months from issuance of these consolidated financial statements, potential changing circumstances, including COVID-19 uncertainties, may result in the depletion of its capital resources more rapidly than it currently anticipates, resulting in the Company not having adequate resources to fund its planned operations and expenditures for at least the next 12 months and to comply with the SVB financial covenant. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

The Company will need to raise additional capital to fund its operations and service its long-term debt obligations until its revenue reaches a level sufficient to provide for self-sustaining cash flows. There can be no assurance that additional capital will be available on acceptable terms, or at all, or that the Company's revenue will reach a level sufficient to provide for self-sustaining cash flows. In addition, the Company must comply with a financial covenant within the Loan Agreement requiring the Company to maintain unrestricted cash of not less than the greater of (i) $12.5 million and (ii) an amount equal to six times the amount of the Company's average monthly Cash Burn (as defined in the Loan Agreement) over the trailing three months. If sufficient additional capital is not available as and when needed, the Company may have to delay, scale back or discontinue one or more product development programs, curtail its commercialization activities, significantly reduce expenses, sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that the Company otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue a sale of the Company at a price that may result in a significant loss on investment for its stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all assets. In addition, if the Company defaults under the Loan Agreement, SVB could accelerate the payment of the SVB Term Loan (see Note 8) and ultimately foreclose on its assets.

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 revenue 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, lease liability, inventory obsolescence and valuation of inventory, accounts receivable and available-for-sale securities. Actual results could materially differ from those estimates, especially in light of the significant uncertainty that remains as to the full impact of the COVID-19 pandemic on the Company's operations, as well as those of its workforce, supply chains, distribution networks and those of its customers.

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 in Available-for-Sale Securities

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. 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. Realized gains, realized losses and declines in value of securities judged to be other-than-temporary, are included in other income (expense) within the 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 securities is also included in other income (expense) within the consolidated statements of operations.

The Company recognizes other-than-temporary impairment ("OTTI") of a debt security for which there has been a decline in fair value below amortized cost if (i) management intends to sell the security, (ii) it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis, or (iii) the Company does not expect to recover the entire amortized cost basis of the security. The amount by which amortized cost exceeds the fair value of a debt security that is considered to have OTTI is separated into a component representing the credit loss, which is recognized in earnings, and a component related to all other factors, which is recognized in other comprehensive income (loss). The measurement of the credit loss component is equal to the difference between the debt security's amortized cost basis and the present value of its expected future cash flows discounted at the security's effective yield. If the Company intends to sell the security, or if it is more likely than not it will be required to sell the security before recovery, an OTTI write-down is recognized in earnings equal to the entire difference between the amortized cost basis and fair value of the security.

Restricted Cash

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 22,397,812	$ 7,619,748
Restricted cash	—	3,270,247
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 22,397,812	$ 10,889,995

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"). Amounts included in restricted cash as of December 31, 2019 represented those required to be set aside in escrow under the terms of the MidCap Credit and Security Agreement (Term Loan) (the "MidCap Term Loan") (see Note 8) to collateralize the payment that would have been due upon maturity of the QNAH Convertible Note (see Note 8). The balance of restricted cash was released to the Company in June 2020 in conjunction with the extinguishment of the QNAH Convertible Note with proceeds from the SVB Term Loan (see Note 8).

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

The NuvoGen obligation relates to an asset purchase transaction with a then-common stockholder of the Company (see Note 10). As of December 31, 2020, the estimated aggregate fair value of the NuvoGen obligation is approximately $4.7 million, determined using a Monte Carlo simulation with key assumptions including future revenue, volatility, discount and risk-free rates.

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. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion and disposal. 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 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, 2020 was $50,855 compared with $79,338 as of December 31, 2019.

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.

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, 2020 and 2019.

Leases

Arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheets as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. For financing leases, interest on the lease liability and the amortization of the right-of-use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded to rent expense as incurred.

In calculating the right-of-use asset and lease liability, the Company elects to combine lease and non-lease components for all classes of assets currently under lease, including facilities and computer equipment. The Company excludes short-term leases having initial terms of 12 months or less as an accounting policy election and recognizes rent expense on short-term leases on a straight-line basis over the lease term for these leases.

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 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 the MidCap Credit and Security Agreement (Revolving Loan) (the "MidCap Revolving Loan") were deferred as an asset in the consolidated balance sheets and amortized on a straight-line basis to interest expense over the term of the revolving commitment until extinguishment of the MidCap Credit and Security Agreement in June 2020 (see Note 8).

Deferred Offering Costs

Deferred offering costs represent legal and other direct costs related to planned future stock offering transactions that will be charged to stockholders' equity upon completion of the proposed stock offering. Should the proposed stock offering prove to be unsuccessful, these deferred costs, as well as any additional expenses to be incurred, will be charged to operating expense in the consolidated statements of operations. There were no deferred offering costs for the year ended December 31, 2020. Deferred offering costs of $0.1 million included as non-current assets in the consolidated balance sheet as of December 31, 2019, represented legal costs incurred by the Company in contemplation of the issuance of additional shares in a future financing transaction. In January 2020, these deferred offering costs were recorded to additional paid in capital, as an offset to proceeds received from the ATM Offering (see Note 14).

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 collaborative 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 with total expected costs as design or development procedures are completed and outputs are produced.

Revenue Recognition

The Company accounts for its revenue in accordance with FASB, ASC 606, *Revenue from Contracts with Customers* ("ASC 606") and ASC 808, *Collaborative Arrangements* ("ASC 808").

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 platform 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. Warranty accrual is included in accrued liabilities in the consolidated balance sheets.

Research and Development Expenses

Research and development expenses represent costs incurred internally for and externally in support of research and development 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 consolidated statements of operations. See Note 9 for further discussion of the development costs associated with collaborative development services agreements included in research and development expense in the consolidated statements of operations.

Stock-based Compensation

The Company incurs stock-based compensation expense relating to grants of restricted stock units ("RSUs") and stock options to employees, consultants and non-employee directors under its equity incentive plans, and stock purchase rights granted under its Employee Stock Purchase Plan ("ESPP").

The Company recognizes expense for stock-based awards 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 accounts for forfeitures as they occur.

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 it is "more likely than not" that the assets will not be recovered 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 more likely than not that net deferred tax assets will not be realized. For the years ended December 31, 2020 and 2019, 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.

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 assets and liabilities are subject to re-measurement, the impact of which is recorded in selling, general and administrative expense 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 consolidated statements of changes in stockholder's equity.

Comprehensive Loss

Comprehensive loss includes certain changes in equity that are excluded from net loss. Specifically, unrealized gains and losses on short-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 institutions, that the credit risk with regard to these deposits is not significant.

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

The Company's top customer accounted for 11% of revenue for the year ended December 31, 2020, compared with the top three customers which accounted for 24%, 22% and 19% for the year ended December 31, 2019. The largest two customers accounted for approximately 9% each of the Company's net accounts receivable as of December 31, 2020. The largest two customers accounted for approximately 29% and 25% of the Company's net accounts receivable at December 31, 2019.

Two vendors accounted for 21% and 20% of the Company's accounts payable as of December 31, 2020 primarily related to commercial operations and inventory purchases compared with one vendor who accounted for 36% and two vendors who accounted for 10% each of the Company's accounts payable at December 31, 2019.

The Company currently relies on a single supplier to manufacture a subcomponent used in its HTG EdgeSeq instruments. 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 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, 2 and 3 fair value measurements. The standard was effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019, with early adoption permitted, including adoption in an interim period. The Company's adoption of this standard on January 1, 2020 did not have a material impact on its consolidated financial statements or related footnote disclosures.

In November 2018, the FASB issued ASU No. 2018-18, which amended ASC 808, *Collaborative Arrangements* ("ASC 808"), and ASC 606 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 was effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019 with early adoption permitted. The Company's adoption of this standard on January 1, 2020 did not have an effect on its consolidated financial statements as it did not change the way collaborative development services and the related costs of these services are reported.

Recent Accounting Pronouncements

The following are recent FASB ASUs that had not been adopted by the Company as of December 31, 2020:

In October 2020, the FASB issued ASC Update No. 2020-10, *Codification Improvements* ("Update No. 2020-10"), which amends a variety of topics in the FASB Accounting Standards Codification (the "Codification") in order to improve the consistency of the Codification and the application thereof, while leaving GAAP unchanged. Update No. 2020-10 is effective for annual periods beginning after December 15, 2020, for public business entities. We plan to adopt Update No. 2020-10 in the first quarter of 2021 and expect it will have an immaterial impact on our financial position and results of operations.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and other Options* (Subtopic 470-20) and *Derivatives and Hedging – Contracts in Entity's Own Equity* (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and also simplifies the diluted earnings per share calculation in certain areas. The standard is effective for public business entities, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years and interim periods within those fiscal years, beginning after December 15, 2021. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, and adoption must be as of the beginning of the Company's annual fiscal year. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects of the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This standard is effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2020. The Company does not expect the adoption of the new guidance under the standard to materially affect its financial position or results of operations.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses*, which was subsequently amended by ASU 2018-19 and ASU 2019-10, 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, 2022 with early adoption permitted. The Company will continue to assess the possible impact of this standard, but currently does not expect 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.

Note 3. Inventory

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

	December 31,	
	2020	2019
Raw materials	$ 1,079,528	$ 872,947
Work in process	147,455	151,351
Finished goods	291,195	284,772
Total gross inventory	1,518,178	1,309,070
Less inventory allowance	$ (26,052)	$ (39,403)
	$ 1,492,126	$ 1,269,667

For the years ended December 31, 2020 and 2019, the Company recorded adjustments to the provision for excess inventory of $56,160 and $153,729, 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 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 measured at fair value on a recurring basis at December 31, 2020 and 2019, respectively, in the fair value hierarchy:

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 17,497,282	$ —	$ —	$ 17,497,282
Corporate debt securities	—	4,499,270	—	4,499,270
Investments available-for-sale at fair value				
Corporate debt securities	—	6,298,075	—	6,298,075
Total	$ 17,497,282	$ 10,797,345	$ —	$ 28,294,627

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 7,217,096	$ —	$ —	$ 7,217,096
Investments available-for-sale at fair value				
U.S. Treasury securities	5,961,983	—	—	5,961,983
Corporate debt securities	—	19,448,239	—	19,448,239
Total	$ 13,179,079	$ 19,448,239	$ —	$ 32,627,318

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, 2020 and 2019.

Level 1 instruments include investments in money market funds and U.S. Treasuries 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, including 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 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, 2020 or 2019 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 high credit quality corporate debt securities as of December 31, 2020. The following is a summary of the Company's available-for-sale securities at December 31, 2020 and 2019:

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
Corporate debt securities	6,298,075	—	—	6,298,075
Total available-for-sale securities	$ 6,298,075	$ —	$ —	$ 6,298,075

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
U.S. Treasury securities	$ 5,962,224	$ 394	$ (635)	$ 5,961,983
Corporate debt securities	19,448,239	—	-	19,448,239
Total available-for-sale securities	$ 25,410,463	$ 394	$ (635)	$ 25,410,222

There were no gross unrealized losses relating to the Company's available-for-sale securities investments as of December 31, 2020. The net adjustment to unrealized holding gains on short-term investments, net of tax in other comprehensive income totaled $9 and $2,299 for the years ended December 31, 2020 and 2019, respectively.

Contractual maturities of debt investment securities at December 31, 2020 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
Corporate debt securities	6,298,075	—	6,298,075
Total available-for-sale securities	$ 6,298,075	$ —	$ 6,298,075

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. As the Company did not have any unrealized losses as of December 31, 2020, there were no other-than-temporary impairments of its available-for-sale securities.

Note 6. Property and Equipment

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

	December 31,	
	2020	2019
Furniture & fixtures	$ 1,082,717	$ 1,089,371
Leasehold improvements	1,943,534	1,987,997
Equipment used in manufacturing	2,166,743	2,305,340
Equipment used in research & development	2,506,644	2,134,019
Equipment used in the field	208,005	182,762
Software	420,301	374,812
Property and equipment	8,327,944	8,074,301
Less: accumulated depreciation and amortization	(7,100,542)	(5,834,168)
	$ 1,227,402	$ 2,240,133

Depreciation and leasehold improvement amortization expense was $1.3 million for both of the years ended December 31, 2020 and 2019.

Note 7. Accrued Liabilities

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

	December 31,	
	2020	2019
Accrued employee bonuses	$ 436,799	$ 900,740
Payroll and employee benefit accruals	694,058	469,530
Accrued interest	61,676	245,350
Other accrued liabilities	267,345	254,676
	$ 1,459,878	$ 1,870,296

Note 8. Debt Obligations.

Current portion of long-term debt, net, consists of the following as of the dates indicated:

	December 31,	
	2020	2019
Convertible note, net of debt issuance costs	$ —	$ 2,987,667
SVB Term Loan payable	2,000,000	—
PPP Loan	857,040	—
Insurance Note Payable	165,099	—
	$ 3,022,139	$ 2,987,667

Long-term debt, net of current portion and discount and debt issuance costs, consisted of the following as of the dates indicated:

	December 31,	
	2020	2019
MidCap Term Loan payable, net of discount and debt issuance costs	$ —	$ 6,871,545
SVB Term Loan payable, net of discount and debt issuance costs	7,708,348	—
PPP Loan	859,960	—
	$ 8,568,308	$ 6,871,545

MidCap Credit Facility

On March 26, 2018 (the “MidCap Closing Date”), the Company entered into the MidCap Term Loan and MidCap Revolving Loan (together 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 provided 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, which was used to repay in full all outstanding amounts and fees due under the Company’s previous Loan and Security Agreement with a syndicate of two lending institutions, Oxford Finance LLC and SVB, as well as for ongoing working capital and general corporate purposes. MidCap Tranche 1 bore interest at a floating rate equal to 7.25% per annum, plus the greater of (i) 1.25% or (ii) the one-month LIBOR.

In February 2020, the MidCap Credit Facility was amended to, amongst other things, extend the interest-only payments on the term loan advances by an additional 11 months, with principal on each term loan advance payable in 25 equal monthly installments beginning March 1, 2021 until paid in full on March 1, 2023. The amendment also provided that if the Company achieved a stated revenue milestone for the 12-month period ending December 31, 2020, the interest-only period would be further extended by an additional four months, with principal on MidCap Tranche 1 then payable in 21 equal monthly installments beginning July 1, 2021. This amendment was accounted for as a modification for accounting purposes.

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 $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 $3.3 million into an escrow account on July 11, 2018. The escrowed funds were released to

the Company on June 25, 2020 in conjunction with the extinguishment of the QNAH Convertible Note with proceeds from the SVB Term Loan (see below).

Unamortized debt discount associated with the MidCap Term Loan of $443,455, resulting from fees and debt issuance costs, was recognized in the consolidated balance sheets as of December 31, 2019. Unamortized costs incurred in connection with the issuance of the Midcap Revolving Loan of $50,970 were presented in other non-current assets in the consolidated balance sheets as of December 31, 2019. There were no unamortized debt discount or revolving loan costs in the consolidated balance sheets as of December 31, 2020.

Amortization of the debt discount associated with the MidCap Term Loan was $93,719 and $166,904 for the years ended December 31, 2020 and 2019, respectively, and was included in interest expense in the consolidated statements of operations. Amortization of deferred MidCap Revolving Loan costs was $7,763 and $16,098 for the years ended December 31, 2020 and 2019, respectively, and is included in interest expense in the consolidated statements of operations.

QNAH Convertible Note

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 incurred simple interest at the rate of 3.0% per annum and matured on October 26, 2020. On June 25, 2020, in connection with the closing of the SVB Term Loan, the Company repaid in full the QNAH Convertible Note and accrued interest in the aggregate amount of $3.2 million.

Extinguishment of MidCap Credit Facility and QNAH Convertible Note upon SVB Term Loan Closing

On June 25, 2020, the Company repaid all principal and interest amounts outstanding under the MidCap Credit Facility in an aggregate amount equal to $7.5 million, including collateral agent legal fees and prepayment fees. The repayment was funded with net proceeds from the SVB Term Loan (see description of the SVB Term Loan below). As a result of the repayment, the Company recorded a loss on extinguishment of the MidCap Credit Facility and the QNAH Convertible Note of $0.5 million, including remaining unamortized discounts of $0.3 million and prepayment and other MidCap Credit Facility and QNAH Convertible Note lender fees and issuance costs in other expense in the consolidated statements of operations for the year ended December 31, 2020. All obligations under the MidCap Credit Facility and the QNAH Convertible Note were fulfilled upon extinguishment of the MidCap Credit Facility.

SVB Term Loan

On June 24, 2020 (the “Closing Date”), the Company entered into a Loan and Security Agreement, by and among the Company and SVB, as lender, which provides a secured term loan in the principal amount of $10.0 million (the “SVB Term Loan”).

The proceeds from the SVB Term Loan were fully funded on the June 25, 2020.

The SVB Term Loan bears interest at a floating rate equal to the greater of 2.50% above the Prime Rate (as defined in the Loan Agreement) and 5.75%. Interest on the SVB Term Loan is due and payable monthly in arrears. The SVB Term Loan has interest-only payments through June 30, 2021. The interest only period may be extended for six months upon the achievement of an equity milestone as fully defined in the Loan Agreement. The ultimate interest-only period will be followed by equal monthly payments of principal and interest through the maturity date of December 1, 2023.

Prepayments of the SVB 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 Closing Date, 2.0% of principal prepaid if prepayment occurs after the first anniversary of the Closing Date but on or prior to the second anniversary of the Closing Date, and 1.0% of principal prepaid if prepayment occurs after the second anniversary of the Closing Date and prior to the maturity date.

Upon termination of the Loan Agreement, the Company is required to pay a final fee equal to 8.00% of the principal amount of the SVB Term Loan.

The Company’s obligations under the Loan Agreement 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 Loan Agreement.

The Loan Agreement 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. The Company must also comply with a financial covenant requiring the Company to maintain unrestricted cash at an account with SVB of not less than the greater of (i) $12.5 million and (ii) an amount equal to six times the amount of the Company's average monthly Cash Burn (as defined in the Loan Agreement) over the trailing three months. While the Company is required to maintain this minimum cash balance, it is not legally restricted by the agreement from withdrawing funds.

The Loan Agreement 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, SVB 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 5.0%.

In connection with the Loan Agreement, the Company granted to SVB a warrant to purchase up to 42,894 shares of the Company's common stock at a purchase price of $11.6565 per share. The warrant will expire on June 24, 2030 and may be exercised for cash or at the election of the holder on a cashless, net exercise basis. The fair value of the warrant on the date of issuance was $0.4 million, determined using the Black-Scholes option-pricing model, and was recorded as a discount to the SVB Term Loan, with a corresponding credit to additional paid in capital since the warrant met the requirements to be classified in equity.

The Company included $1.1 million of debt discount associated with the SVB Term Loan, resulting from fees and debt issuance costs, inclusive of the fair value of warrants issued, in long-term debt, net in the consolidated balance sheets as of December 31, 2020. Amortization of the debt discount associated with the SVB Term Loan was $0.2 million for the year ended December 31, 2020 and was included in interest expense in the consolidated statements of operations. The effective interest rate for the year ended December 31, 2020 was 11.11%.

The remaining principal repayments due under the SVB Term Loan as of December 31, 2020 are as follows for each fiscal year:

2021	$	2,000,000
2022		4,000,000
2023		4,000,000
Total SVB Term Loan payments		10,000,000
Less discount and deferred financing costs		(1,091,652)
Plus final fee premium		800,000
Total SVB Term Loan, net	$	9,708,348

Paycheck Protection Program Loan

On April 21, 2020, the Company received proceeds from a loan in the amount of $1.7 million from SVB, as lender, pursuant to the Paycheck Protection Program of the CARES Act. The PPP Loan is evidenced by a promissory note (the "Note"), which contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties or terms of the PPP Loan documents.

The PPP Loan matures on April 21, 2022 and bears interest at an annual rate of 1%. Beginning on September 21, 2021, the Company is required to make eight equal monthly payments of principal and interest. The PPP Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties. The proceeds from the PPP Loan may only be used for payroll costs (including benefits), rent and utility obligations, and interest on certain of the Company's other debt obligations.

All or a portion of the PPP Loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application and documentation by the Company of expenditures in accordance with the SBA requirements. Under the CARES Act and PPP Flexibility Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 24-week period beginning on the date of loan approval. For purposes of the PPP, payroll costs exclude compensation of an individual employee in excess of $100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if a Company's full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25% during the measurement period, unless certain safe harbors are

satisfied. In the event the PPP Loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal and interest. The Company applied for full PPP Loan forgiveness in October 2020. However, there can be no assurance given that the Company will obtain forgiveness of the PPP Loan in whole or in part. In order to apply for the PPP Loan, the Company certified that, among other things, the current economic uncertainty made the PPP Loan request necessary to support its ongoing operations. In addition, PPP loans under the CARES Act may be subject to certain rules, regulations and Standard Operating Procedures ("SOPs") applicable to the SBA's Section 7(a) Loan Program, which includes PPP loans under the CARES Act. The interpretation and applicability of these rules, regulations and SOPs is unclear, as some of them have not been referenced in the CARES Act itself or in the guidance and interpretations issued by the SBA to date. If it is determined that the Company was not eligible to receive the PPP Loan, or that the Company has not adequately complied with the rules, regulations and SOPs applicable to the SBA's Section 7(a) Loan Program, the Company could be subject to penalties and could be required to repay the PPP Loan in its entirety.

Insurance Note

On April 27, 2020, the Company entered into the Insurance Note to extend the payment period related to its director and officer insurance policy. The Insurance Note required a down payment to be made upon signing the agreement equal to $0.2 million. The unpaid premium balance of $0.7 million was financed at an annual rate of 3.61%. The Insurance Note is being repaid in nine equal monthly payments of principal and interest beginning on June 6, 2020. The Insurance Note contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties or terms of the Insurance Note documents. The Insurance Note may be prepaid by the Company at any time prior to maturity with no prepayment penalties.

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, 2020 and 2019 as follows:

	Years Ended December 31,	
	2020	2019
Product revenue:		
Instrument	$ 869,035	$ 1,436,730
Consumables	3,030,612	3,010,094
Total product revenue	3,899,647	4,446,824
Product-related services revenue:		
Custom RUO assay design	1,393,316	4,498,088
RUO sample processing	2,597,891	5,687,292
Total product-related services revenue	3,991,207	10,185,380
Total product and product-related services revenue	$ 7,890,854	$ 14,632,204

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 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 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. Standard delivery terms for sales to customers outside of the United States are FOB delivery point, unless otherwise specified in the customer contract. 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

RUO 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 with 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.

The Company did not recognize any custom RUO assay design revenue from performance obligations that were satisfied in previous periods during the year ended December 31, 2020 compared with $41,137 for the year ended December 31, 2019.

Collaborative Development Services Revenue

The Company enters into collaborative development services agreements with biopharmaceutical companies for the development of NGS-based companion diagnostic assays in support of and in conjunction with, biopharmaceutical companies' drug development programs. These collaborative development services agreements may generate upfront fees, and in some cases subsequent milestone payments that may be earned upon completion of certain product development milestones or activities. The Company follows ASC 606 and ASC 808 to determine the appropriate recognition of revenue under its collaborative research, development and commercialization agreements. Collaborative development services revenue related to these contracts for the years ended December 31, 2020 and 2019 was generated through statements of work entered into under the Governing Agreement with QIAGEN Manchester Limited ("QML") as discussed below.

	Years Ended December 31,	
	2020	2019
Collaborative development services	$ 658,010	$ 4,571,684

Master Assay Development, Commercialization and Manufacturing Agreement

In November 2016, the Company entered into a Master Assay Development, Commercialization and Manufacturing Agreement with QML (the "Governing Agreement"). The Governing Agreement created the framework for QML and the Company to combine their technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays. Under the Governing Agreement, the parties jointly sought companion diagnostic programs with biopharmaceutical companies, with QML entering into sponsor project agreements with interested biopharmaceutical companies for specified projects, and QML and the Company entering into statements of work which set forth the rights and obligations of QML and the Company with respect to each project. In November 2019, the Company elected to terminate the Governing Agreement with QML. The Company's termination of the Governing Agreement did not terminate active statements of work under the Governing Agreement, namely SOW Two and SOW Three (each defined below).

The Company has determined that 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 the Company a monthly fee for development work performed by the Company and its subcontractors (collectively, the "Monthly Fee"). The Monthly Fee is based on the employee and materials costs incurred during the month, which is subject to significant variability from period to period and unknown until the costs are incurred. Therefore, the Monthly Fee, which is based on use of hours and costs as a measure of progress, is included in the transaction price and recognized as revenue over time when the costs are incurred, and the Monthly Fee is billed to QML. It is at this time that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company and QML also share any net profits resulting from performance of the development work as determined pursuant to the Governing Agreement. Such profit-sharing payment(s) are deemed to be variable consideration using the expected value method and are 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. 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 two additional times in September 2018 and February 2019.

The initial-phase investigational-use-only ("IUO") development activities under SOW Two and the first three amendments related to next phases, which included the use of the IUO assay developed in the initial-phase in a retrospective clinical trial and in additional disease indications were completed prior to 2020. Development activities agreed upon in the fourth amendment of SOW Two were completed in the fourth quarter of 2020. As of December 31, 2020, there are no additional agreed upon development activities to be completed under SOW Two.

Revenue of $0.7 million, inclusive of SOW Two Monthly Fees and $0.2 million of SOW Two profit-sharing payments has been included in collaborative development services revenue in the consolidated statements of operations for the year ended December 31, 2020. Revenue of $2.7 million, inclusive of SOW Two Monthly Fees and $0.7 million of SOW Two profit-sharing payments has been included in collaborative development services revenue in the consolidated statements of operations for the year ended December 31, 2019. Accounts receivable relating to SOW Two of $0.1 million and $0.2 million remained in the consolidated balance sheets as of December 31, 2020 and 2019, respectively. Costs relating to development activities conducted by the Company pursuant to SOW Two of $0.5 million have been included in research and development expense in the consolidated statements of operations for the year ended December 31, 2020, compared with $1.8 million for the year ended December 31, 2019.

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. Initial assay development activities under SOW Three were completed prior to 2020 and development procedures contemplated in the first amendment to SOW Three have remained on hold throughout 2020, pending customer decision as to whether to proceed with next phase contract activities.

There was no revenue recognized, or development costs incurred relating to SOW Three for the year ended December 31, 2020. Revenue of $1.9 million, inclusive of SOW Three Monthly Fees and $0.7 million of SOW Three profit-sharing payments has been included in collaborative development services revenue in the consolidated statements of operations for the year ended December 31, 2019. Accounts receivable relating to SOW Three of $0.8 million remained in the consolidated balance sheets as of December 31, 2019. Costs relating to development activities conducted by the Company pursuant to SOW Three of $1.0 million have been included in research and development expense in the consolidated statements of operations for the year ended December 31, 2019.

Contract Liabilities

The Company receives up-front payments from customers for custom RUO assay design and sample processing services. In addition, payments for instrument extended warranty contracts are required to be made in advance. The Company recognizes such up-front payments as contract liabilities. The contract liabilities are subsequently reduced at the point in time that the data files are delivered for sample processing services or as the Company satisfies its performance obligations over time for RUO assay design and extended warranty services. Contract liabilities of $0.2 million and $0.6 million were included in contract liabilities – current and other non-current liabilities in the consolidated balance sheets as of December 31, 2020 and 2019, respectively.

Changes in the Company's contract liabilities were as follows as of the dates indicated:

	Product Revenue	Custom RUO Assay Design	Sample Processing	Total Contract Liability
Balance at January 1, 2020	$ 95,148	$ 66,216	$ 438,090	$ 599,454
Deferral of revenue	500,045	566,733	124,404	1,191,182
Recognition of deferred revenue	(491,613)	(632,949)	(186,888)	(1,311,450)
Transfer to refund liability	—	—	(281,722)	(281,722)
Balance at December 31, 2020	$ 103,580	$ —	$ 93,884	$ 197,464

	Product Revenue	Custom RUO Assay Design	Sample Processing	Total Contract Liability
Balance at January 1, 2019	$ 116,547	$ 50,000	$ 244,400	$ 410,947
Deferral of revenue	218,802	972,267	529,913	1,720,982
Recognition of deferred revenue	(240,201)	(956,051)	(336,223)	(1,532,475)
Balance at December 31, 2019	$ 95,148	$ 66,216	$ 438,090	$ 599,454

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 agreed to pay total aggregate cash compensation to NuvoGen under the agreement of $15.0 million. 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 is obligated to pay the greater of $0.4 million or 6% of annual revenue until the obligation is paid in full. The Company paid yearly fixed fees, in quarterly installments, to NuvoGen of $0.4 million as well as revenue-based payments of $0.2 million and $0.9 million during the years ended December 31, 2020 and 2019, respectively, for the amount by which 6% of revenue exceeded the applicable fixed fee. Beginning on January 1, 2019 and continuing until the remaining obligation has been paid in full, interest on the remaining unpaid obligation is being accrued and will compound annually at a rate of 2.5% per year. Accrued interest related to this obligation is payable on the date that the remaining obligation is paid in full.

Minimum payments to be made in 2021 include $54,777 of revenue-based payments payable as of December 31, 2020 and an estimate of additional revenue-based payments to be made throughout the remainder of 2021 relating to revenue generated in the first, second and third quarters of 2021 using actual revenue generated in the same quarters in 2020. 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 those years exceeds $0.4 million:

2021	$	512,729
2022		400,000
2023		400,000
2024		400,000
2025		400,000
2025 and beyond		2,800,021
Total NuvoGen obligation payments		4,912,750
Plus interest accretion		79,376
Total NuvoGen obligation, net	$	4,992,126

The Company has recorded the obligation at the estimated present value of the future payments using a discount rate of 2.5%, which represents the Company's estimate of its effective borrowing rate for similar obligations. The unamortized interest accretion was $(79,376) and $(92,311) at December 31, 2020 and 2019, respectively. Discount accreted during the years ended December 31, 2020 and 2019 was $(12,935), and $(13,821), respectively.

Note 11. Leases

Operating Leases

The Company leases office space and equipment under agreements classified as operating leases that expire on various dates through 2023. The Company's most significant active leases as of December 31, 2020 are for office and manufacturing space in Tucson, Arizona and a development laboratory space in San Carlos, California.

The Company amended its Tucson facility leases in December 2020 to extend the terms for one year, through January 31, 2022. The lease extension, treated as a lease modification for accounting purposes, allows for an additional extension of three years upon the same terms and conditions of the existing amended lease agreements, except that the lease rates would be adjusted to reflect lease rates applicable to like-kind buildings within the market at the time that the Company elects to exercise the extension option, but in no event less than the last applicable rental rate.

The Company's leases do not include any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses. Renewal options have not been included in the calculation of the Company's lease liabilities and right-of-use assets as of December 31, 2020, as the Company is not reasonably certain to exercise the options. Annual rent increases are included in the calculation of the operating lease right-of-use assets. Variable expenses generally represent the Company's share of the landlord's operating expenses and are recorded when incurred. Incremental borrowing rates used to discount future lease payments in calculating lease liabilities were estimated by reference to the rates for similar length secured lines of credit to the Company's lease agreements provided by the Company's lenders at the time that the lease liabilities were recorded, as these rates represented the cost of borrowing for secured loans of similar duration. The Company does not have any operating lease arrangements where it acts as a lessor.

The components of lease cost for operating leases were as follows:

	Years Ended December 31,	
	2020	2019
Operating leases		
Operating lease cost	$ 752,413	$ 618,463
Variable lease cost	125,792	131,387
Operating lease expense	878,205	749,850
Short-term lease rent expense	—	1,497
Total rent expense	$ 878,205	$ 751,347

The table below summarizes other information related to the Company's operating leases:

	Years Ended December 31,	
	2020	2019
Cash paid for amounts included in measurement of operating lease liabilities	$ 883,252	$ 770,658
Establishment of operating lease liabilities arising from obtaining right-of-use assets	$ 515,409	$ 2,038,193
Weighted-average remaining lease term – operating leases	1.7	2.3
Weighted-average discount rate – operating leases	8.0%	9.6%

As of December 31, 2020, remaining maturities of the Company's operating leases, excluding short-term leases, are as follows:

2021	$ 746,724
2022	319,678
2023	70,848
Total	1,137,250
Less present value discount	(83,348)
Total operating lease liabilities	1,053,902
Less operating lease liabilities - current	(685,220)
Non-current operating lease liabilities - non-current	$ 368,682

Financing Leases

The Company has a number of computer and copier equipment leases that are classified as financing leases. Incremental borrowing rates used to discount future lease payments in calculating lease liabilities were estimated by reference to information received by the Company from bankers regarding estimated current borrowing rates for collateralized loans with similar amount and duration as the leases. The Company does not have any material financing leases where it acts as a lessor. The components of lease cost for financing leases were as follows:

	Years Ended December 31,	
	2020	2019
Financing leases		
Amortization of right-of-use assets	$ 42,826	$ 46,255
Interest on lease liability	8,938	6,859
Total financing lease cost	$ 51,764	$ 53,114

The table below summarizes other information related to the Company's financing leases:

	Years Ended December 31,	
	2020	2019
Weighted-average remaining lease term – financing leases	3.4	3.7
Weighted-average discount rate – financing leases	9.77%	9.77%

As of December 31, 2020, remaining maturities of the Company's financing leases are as follows:

2021	$ 28,355
2022	20,716
2023	18,396
2024	16,080
Total	83,547
Less present value discount	(12,873)
Financing lease liabilities, net	$ 70,674

As of December 31, 2020, the Company had financing lease liabilities net of discount of $70,674, of which $22,563 was included in other current liabilities and $48,111 was included in other non-current liabilities, and financing right-of-use assets of $66,770, which were included in property and equipment, net, in the consolidated balance sheets.

Note 12. 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.

In September 2019, in connection with the Securities Purchase Agreement (see Note 14), the Company issued and sold pre-funded warrants exercisable for an aggregate of 360,779 shares of common stock. The total exercise price of the pre-funded warrants is $9.75 per share, $9.60 of which was pre-funded and paid to the Company upon issuance of the pre-funded warrants. The remaining exercise price of the pre-funded warrants is $0.15 per share. The pre-funded warrants are exercisable by the holders at any time and do not expire. In March 2020, prefunded warrants representing 211,784 shares of the Company's common stock were exercised for proceeds of $31,768. The remaining pre-funded warrants are immediately exercisable and do not expire. As the remaining shares underlying the pre-funded warrants are issuable for nominal consideration of $0.15 per share, 148,995 in common shares underlying the unexercised pre-funded warrants were considered outstanding for purposes of the calculation of loss per share as of December 31, 2020.

In connection with the SVB Term Loan (see Note 8), the Company granted SVB a warrant to purchase up to 42,894 shares of the Company's common stock at a purchase price of $11.6565 per share. The warrant will expire on June 24, 2030 and may be exercised for cash or, at the election of the holder, on a cashless, net exercise basis.

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,	
	2020	2019
Numerator:		
Net loss	$ (20,870,218)	$ (19,297,664)
Denominator:		
Weighted-average shares outstanding-basic and diluted *	4,627,918	2,539,979
Net loss per share, basic and diluted	$ (4.51)	$ (7.60)

*Reflects the retrospective adjustment related to the reverse stock split completed on November 20, 2020.

The following common stock equivalents 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,	
	2020	2019
Options to purchase common stock	487,227	193,660
Series A Preferred	158,545	—
Common stock warrants	58,689	15,794
Restricted stock units	12,214	14,916
QNAH convertible note	—	53,357

Note 13. Warrants

In connection with certain of its redeemable convertible preferred stock issuances, debt agreements, convertible debt 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.

In connection with the Securities Purchase Agreement (see Note 14), the Company issued and sold pre-funded warrants exercisable for an aggregate of 360,779 shares of common stock. The total exercise price of the pre-funded warrants is $9.75 per share, $9.60 of which was pre-funded and paid to the Company upon issuance of the pre-funded warrants. The remaining exercise price of the pre-funded warrants is $0.15 per share. The pre-funded warrants are exercisable by the holders at any time and do not expire. In March 2020, prefunded warrants representing 211,784 shares of the Company's common stock were exercised for proceeds of $31,768. As of December 31, 2020, pre-funded warrants to purchase an aggregate of 148,995 shares of the Company's common stock were outstanding.

In connection with the SVB Term Loan (see Note 8), the Company granted SVB a warrant to purchase up to 42,894 shares of the Company's common stock at a purchase price of $11.6565 per share. The warrant will expire on June 24, 2030 and may be exercised for cash or, at the election of the holder, on a cashless, net exercise basis.

The following table shows the common stock warrants outstanding as of December 31, 2020:

Warrant Issuance Date	Shares of Common Stock Underlying Warrants	Exercise Price/Share	Expiration Date
August 2014	1,914	$ 352.65	2024
December 2014	9,651	210.00	2022
March 2016	3,021	41.40	2026
March 2018	1,208	115.95	2028
September 2019	148,995	0.15	N/A
June 2020	42,894	11.6565	2030

Note 14. Stockholders' Equity

Public and Private Offerings

2019 Underwritten Public and Private Offerings

Public Offering

In September 2019, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co. ("Cantor"), relating to the issuance and sale in a public offering of 1,953,236 shares of its common stock, including 254,770 shares sold pursuant to the full exercise of the underwriter's option to purchase additional shares. The price to the public in the offering was $9.75 per share and the underwriter agreed to purchase the shares from the Company pursuant to the Underwriting Agreement at a price of $9.165 per share. The net proceeds to the Company were $17.7 million, after deducting the underwriting discounts and commissions and offering expenses.

The offering was made pursuant to the Company's registration statement on Form S-3 (Registration Statement No. 333-229045), previously filed with the Securities and Exchange Commission ("SEC") and declared effective by the SEC on February 11, 2019, and a prospectus supplement and accompanying prospectus thereunder.

Securities Purchase Agreement

In September 2019, concurrent with the closing of the September 2019 underwritten public offering, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional accredited investors (the "Purchasers"), pursuant to which the Company sold to the Purchasers, in a private placement transaction, warrants to purchase up to an aggregate of 360,779 shares of its common stock ("Warrant Shares"), at a price of $9.60 per warrant (which $9.60 price relates to the pre-funded portion of the total $9.75 exercise price per share). Each pre-funded warrant has a remaining exercise price of $0.15 per share and became immediately exercisable upon issuance, subject to certain beneficial ownership limitations.

The exercise price of the pre-funded warrants will be subject to adjustment in the event of any stock dividends and splits, recapitalization, reorganization or similar transaction, as described in the pre-funded warrants. The pre-funded warrants are exercisable on a "cashless" basis in certain circumstances.

Cantor (the "Placement Agent") acted as the sole placement agent in connection with the private placement of the warrants. Pursuant to a Placement Agency Agreement between the Company and the Placement Agent, the Company agreed to pay the Placement Agent a cash fee equal to 6% of the gross proceeds from the sale of the pre-funded warrants, and to provide reimbursement for certain out-of-pocket expenses. Upon closing, the Company received $3.1 million in net proceeds from the sale of the pre-funded warrants in the private placement, which does not include proceeds that may be received upon exercise of the pre-funded warrants, after deducting the Placement Agent fee and other expenses. In March 2020, 211,784 of the pre-funded warrants were exercised for additional proceeds of $31,768.

ATM Offering

In November 2019, the Company entered into a Controlled Equity Offering Sales Agreement (the "Cantor Sales Agreement") with Cantor as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value $0.001 per share, having an aggregate offering price of up to $20.0 million, by any method deemed to be an "at the market offering" as defined by rule 415(a)(4) under the Securities Act (the "ATM Offering"). The shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-229045).

Approximately $81,000 of costs incurred in connection with the offering were capitalized as deferred offering costs in the Company's consolidated balance sheets upon entry into this agreement in addition to the Form S-3 costs capitalized under a previous ATM offering that was never activated of which $45,000 were reimbursable by Cantor through reduction of commissions earned on shares sold under the Cantor Sales Agreement. The Company is not obligated to sell any shares under the Cantor Sales Agreement and pays Cantor a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, has reimbursed legal fees and disbursements and has provided Cantor with customary indemnification and contribution rights. The Cantor Sales Agreement may be terminated by Cantor or the Company at any time upon notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material and adverse change in the Company's business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares.

During the year ended December 31, 2020, the Company sold 955,240 shares of common stock under the ATM Offering at then-market prices for total gross proceeds of $7.9 million. After deferred offering costs included as non-current assets in the consolidated balance sheets as of December 31, 2019 of $0.1 million and paying sales commissions owned in connection with the ATM Offering of $0.2 million, the Company's aggregate net proceeds for the year ended December 31, 2020 were $7.5 million. There were no shares sold under the Cantor Sales Agreement through December 31, 2019. See Note 17 for further information regarding the ATM Offering.

Exchange and Private Placement

On February 25, 2020, the Company entered into an Exchange and Purchase Agreement (the "Exchange Agreement") with certain accredited investors (the "Investors") pursuant to which the Company agreed to (i) issue to the Investors an aggregate of 41,100 shares of its newly designated Series A Convertible Preferred Stock, par value $0.001 per share ("Series A Preferred"), in exchange for the Investors surrendering to the Company for cancellation an aggregate of 274,000 shares of its common stock (the "Exchange") and (ii) sell and issue to the Investors an aggregate of 10,170 shares of Series A Preferred for an aggregate purchase price of $0.6 million, or $59.00 per share (the "Private Placement"), both of which were completed prior to the end of February 2020.

In February 2020, in connection with the Exchange Agreement and the planned issuance of shares of Series A Preferred pursuant to the Exchange and Private Placement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Series A Certificate of Designation"). The Series A Certificate of Designation establishes and designates the Series A Preferred and the rights, preferences and privileges thereof.

Each share of Series A Preferred is convertible into 6.67 shares of the Company's common stock, subject to proportional adjustment and beneficial ownership limitations. In June 2020, certain of the Investors elected to convert 27,500 shares of Series A Preferred to

common stock in the aggregate, resulting in the issuance of 183,333 shares of the Company's common stock. The remaining 23,770 Series A Preferred shares remain outstanding as of December 31, 2020.

In the event of the Company's liquidation, dissolution or winding up, holders of Series A Preferred will participate pari passu with any distribution of proceeds to holders of the Company's common stock. Holders of Series A Preferred are entitled to receive dividends on shares of Series A Preferred equal (on an as converted to common stock basis) to and in the same form as dividends actually paid on the Company's common stock. Shares of Series A Preferred generally have no voting rights, except as required by law.

LP Purchase Agreement

On March 24, 2020, the Company entered into a purchase agreement ("LP Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to sell to Lincoln Park up to $20.0 million of shares of its common stock ("Purchase Shares") from time to time over the 36-month term of the LP Purchase Agreement. The Company may sell up to 20,000 shares of its common stock to Lincoln Park in a regular purchase on any single business day that the closing price of its stock is not below $1.50. The minimum purchase amount per day must be equal to or greater than $150,000 to the extent the Company chooses to sell shares to Lincoln Park. This amount may be increased to up to 23,333 shares if the closing price of the Company's common stock is not below $7.50 and to up to 26,666 shares if the closing price of the Company's common stock is not below $11.25. In each case, the maximum amount of any single business day's Purchase Shares may be increased up to 166,666 shares. The Company may direct Lincoln Park to purchase shares as often as every business day subject to the limitations outlined above. For each sale of common stock during the period of the agreement, the purchase price of the Purchase Shares will be established by a formula based on the recent closing prices of the Company's common stock leading up to the date of sale. In addition to the regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sales price of the Company's common stock exceeds certain threshold prices as set forth in the LP Purchase Agreement.

Under applicable rules of The Nasdaq Capital Market, in no event may the Company issue or sell to Lincoln Park under the LP Purchase Agreement shares of its common stock in excess of 19.99% of the shares of the Company's common stock outstanding immediately prior to execution of the LP Purchase Agreement (the "Exchange Cap"), unless (i) the Company obtains stockholder approval to issue shares of its common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of its common stock to Lincoln Park under the LP Purchase Agreement equals or exceeds $5.2155, such that issuances and sales of the common stock to Lincoln Park under the purchase agreement would be exempt from the issuance limitation under applicable Nasdaq rules. The Company determined that the right to sell additional shares represents a freestanding put option under derivative accounting guidance, but has a fair value of zero, and therefore no additional accounting was required.

Lincoln Park has no right to require the Company to sell any shares of its common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as directed by the Company, subject to the limitations outlined above. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the LP Purchase Agreement if doing so would result in Lincoln Park beneficially owning more than 9.99% of the Company's common stock.

The Company issued Lincoln Park an aggregate of 41,026 shares of its common stock as consideration for their purchase commitment pursuant to the LP Purchase Agreement. During the year ended December 31, 2020, the Company sold 197,632 shares of common stock under the LP Purchase Agreement at a weighted average price of $4.94 per share for total gross proceeds of $1.0 million. Additional sales of shares of common stock to Lincoln Park under the LP Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, trading price of the Company's common stock and determinations by the Company as to the appropriate sources of funding for the Company.

Common Stock

On November 20, 2020, the Company completed a reverse stock split of its outstanding shares of common stock pursuant to which every fifteen (15) shares of issued and outstanding common stock were exchanged for one share of its common stock. No fractional shares were issued in the reverse stock split. Instead, fractional shares that would have otherwise resulted from the stock split were purchased by us at the applicable percentage of $4.27 per share. All share and per share amounts included within these financial statements have been retrospectively adjusted to reflect the reverse stock split.

Pursuant to its amended and restated certificate of incorporation, the Company is authorized to issue 26,666,667 shares of common stock at a par value of $0.001 per share. 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.

Preferred Stock

Pursuant to its amended and restated certificate of incorporation, the Company has been authorized to issue 10,000,000 shares of preferred stock, each having a par value of $0.001. The preferred stock may be issued from time to time in one or more series with the authorization of the Company's Board of Directors. The Board of Directors can determine voting power for each series issued, as well as designation, preferences, and relative, participating, optional or other rights and such qualifications, limitations or restrictions thereof.

Stock-based Compensation

The Company incurs stock-based compensation expense relating to the grants of RSUs and stock options to employees, non-employee directors and consultants under its equity incentive plans and through stock purchase rights granted under the ESPP.

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 May 2015, the 2011 Plan terminated, and no further awards were granted under the 2011 plan upon the effective date of the Company's 2014 Equity Incentive Plan (the "2014 Plan").

There were no shares of the Company's stock available for issuance under the 2014 Plan as of December 31, 2019, other than those reserved for inducement awards, as outlined below. On January 1, 2020, an additional 154,907 shares were registered for issuance under the 2014 Plan pursuant to an evergreen provision contained in the 2014 Plan.

In May 2019, 13,333 shares were reserved for issuance under the 2014 Plan pursuant to an amendment approved by the Company's Board of Directors pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules, to be used exclusively for the grant of awards to individuals who were not previously employees or non-employee directors of the Company, as inducement material to the individuals' entering into employment with the Company ("Inducement Awards").

In August 2020, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the 2020 Equity Incentive Plan (the "2020 Plan") as a successor to and continuation of the 2014 Plan. Upon approval of the 2020 Plan, 744,685 shares, including 68,552 remaining shares reserved for issuance under the 2014 Plan (excluding shares available for the granting of Inducement Awards under the 2014 Plan's inducement share pool), were reserved for issuance under the 2020 Plan. No new awards may be granted under the 2014 Plan.

There were 513,619 shares of the Company's common stock available for issuance under the 2020 Plan as of December 31, 2020 in addition to shares that may become available from time to time as shares of our common stock subject to outstanding awards granted under the 2014 Plan (excluding Inducement Awards), the 2011 Plan or the 2001 Plan that, following the effective date of the 2020 Plan (i) are not issued because such award or any portion thereof expires or otherwise terminates without all of the shares covered by such award having been issued; (ii) are not issued because such award or any portion thereof is settled in cash; or (iii) are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares. The 2020 Plan does not contain an evergreen provision.

The Company's Board of Directors determines the grant date for all awards granted under the 2020 Plan. The exercise price of stock options granted is generally equal to the closing price of the Company's common stock on the date of grant or on the employee's hire date for new hire grants. All stock options granted have a ten-year term. The vesting period of stock options and RSUs is established by the Company's Board of Directors but typically ranges between one and four years.

Amounts recognized in the consolidated statements of operations with respect to the Company's equity incentive plans were as follows:

	Years Ended December 31,	
	2020	2019
Selling, general and administrative	$ 1,461,190	$ 859,653
Research and development	106,267	243,804
Cost of product and product-related services revenue	17,328	53,110
	$ 1,584,785	$ 1,156,567

The following table summarizes stock option activity during the two-year period ended December 31, 2020:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at January 1, 2019	136,482	$ 46.05	7.6	$ 366,007
Granted	84,667	22.20		
Exercised	(3,617)	33.45		$ 21,380
Forfeited	(10,771)	49.35		
Expired/Cancelled	(13,101)	48.45		
Balance at December 31, 2019	193,660	$ 35.55	8.0	$ 781
Granted	387,178	7.81		
Exercised	-	-		$ -
Forfeited	(67,369)	12.99		
Expired/Cancelled	(26,242)	32.04		
Balance at December 31, 2020	487,227	$ 16.78	8.6	$ 1,536
Exercisable at December 31, 2019	92,058	42.60	6.6	$ 1,440
Exercisable at December 31, 2020	187,031	27.07	7.5	$ 305

The weighted-average fair value of stock options granted was $6.40 and $14.55 for the years ended December 31, 2020 and 2019, respectively. The 2019 stock option activity includes 5,333 Inducement Awards granted during the year ended December 31, 2019 compared with no Inducement Awards granted during the year ended December 31, 2020. As of December 31, 2020, total unrecognized compensation cost related to stock option awards was approximately $2.3 million, which is expected to be recognized over approximately 2.29 years.

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:

	2020	2019
Fair value of common stock on grant date	$4.35 - 11.25	$10.20 - 33.90
Risk-free interest rate	0.34% - 1.65%	1.43% - 2.21%
Expected volatility	109.1% - 149.9%	63.9% - 97.1%
Expected term	5.4 to 5.9 years	5.5 to 6.1 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 for the year ended December 31, 2020, and of the Company's common stock as well as that of publicly traded industry competitors for the year ended December 31, 2019, 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, 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, 2020:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at January 1, 2019	15,180	$ 49.50
Granted	5,167	28.95
Released	(5,431)	49.65
Balance at December 31, 2019	14,916	$ 43.65
Granted	7,000	7.83
Released	(7,911)	35.85
Forfeited	(1,791)	41.23
Balance at December 31, 2020	12,214	$ 28.61
Vested and unissued at December 31, 2020	1,390	$ 33.21

The weighted-average fair value of RSUs granted was $7.83 and $28.95 for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, total unrecognized compensation cost related to RSU awards was approximately $0.3 million, which is expected to be recognized over approximately 1.69 years.

Vested and unissued awards at December 31, 2020 represents RSU awards granted in August 2018, January 2019, September 2019 and August 2020 for which a portion of the awards vested on December 31, 2020, but for which issuance of shares occurred in January 2021.

2014 Employee Stock Purchase Plan

In April 2015, the Company's stockholders approved the 2014 Employee Stock Purchase Plan, which became effective in May 2015. 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 lesser 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) 13,000 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.

Amounts recognized in the consolidated statements of operations with respect to the ESPP were as follows:

	Years Ended December 31,	
	2020	2019
Selling, general and administrative	$ 12,106	$ 43,615
Research and development	5,248	18,454
Cost of product and product-related services revenue	3,832	4,169
	$ 21,186	$ 66,238

During the year ended December 31, 2020, employees entering the plan at various times throughout the offering period purchased the following shares at the end of each of the ESPP's six-month purchase periods:

	June 2020		December 2020	
	Number of Shares	Price per Share	Number of Shares	Price per Share
ESPP Group:				
Group A	3,033	$ 8.29	2,857	$ 4.87
Group B	-	N/A	396	4.87
Total number of shares purchased	3,033		3,253	

During the year ended December 31, 2019, employees entering the plan at various times throughout the offering period purchased the following shares at the end of each of the ESPP's six-month purchase periods:

	June 2019		December 2019	
	Number of Shares	Price per Share	Number of Shares	Price per Share
ESPP Group:				
Group A	1,972	$ 23.59	1,830	$ 8.55
Group B	389	26.78	349	8.55
Group C	305	26.78	320	8.55
Group D	-	N/A	165	8.55
Total number of shares purchased	2,666		2,664	

As of December 31, 2020, approximately 24,922 shares of the Company's common stock were reserved for future issuance under the ESPP. On January 1, 2021, an additional 13,000 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:

	2020	2019
Fair value of common stock	$8.70 - 9.75	$27.75 - 60.00
Risk-free interest rate	0.18% - 1.58%	1.88% - 2.37%
Expected volatility	65.8% - 88.9%	79.5% - 85.8%
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 volatility of the Company's common stock in recent periods for the year ended December 31, 2020, and of the Company's common stock as well as that of publicly traded industry competitors for the year ended December 31, 2019, 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 16,666 shares of common stock, and a maximum of 500 shares of common stock may be purchased by any one participant on any one purchase date. The Board of Directors or an authorized committee must review and approve each individual request to purchase common stock under the Purchase Plan. No stock was sold under the Purchase Plan during the year ended December 31, 2020. Cash received from the sale of common stock by the Company to eligible participants for the year ended December 31, 2019 was $17,250, which resulted in the sale of 500 shares of the Company's common stock at fair market value. As of December 31, 2020, there were 11,658 shares available for issuance under the Purchase Plan.

Note 15. Commitments and Contingencies

Legal Matters

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

Employee Agreements

The Company has entered into Severance and Change in Control Plan agreements with certain named executive officers and various other members of management, which provide salary continuation payments, bonuses and, in certain instances, the acceleration of the vesting of certain equity awards to individuals in the event that the individual is terminated other than for cause, as defined in the applicable 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.

Product Warranty

The following is a summary of the Company's general product warranty liability, which is included in accrued liabilities in the consolidated balance sheets for the years ended December 31, 2020 and 2019:

	Years Ended December 31,	
	2020	2019
Beginning balance	$ 94,482	$ 63,461
Cost of warranty claims	(32,866)	(40,055)
Increase in warranty reserve	31,080	71,076
Ending balance	$ 92,696	$ 94,482

Defined Contribution Plan

In January 2003, the Company established a defined contribution plan ("401(k) Plan") under section 401(k) of the Internal Revenue Code of 1986, as amended (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, 2020 and 2019.

Note 16. 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, income tax expense has been recorded for state minimum and foreign income 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 $3.0 million and $2.7 million of uncertain tax positions as of December 31, 2020 and 2019, respectively, related to certain tax credit carryforwards.

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, 2020 or 2019, and has not recognized interest or penalties during the years ended December 31, 2020 and 2019, since there was no reduction in income taxes paid due to uncertain tax positions. Management of the Company believes no significant change to the amount of unrecognized tax benefits will occur within the next 12 months.

The following table summarizes loss before income taxes:

	Years Ended December 31,	
	2020	2019
U.S. pre-tax loss	$ (20,855,184)	$ (19,332,809)
Foreign pre-tax gain (loss)	(619)	38,524
Loss before income taxes	$ (20,855,803)	$ (19,294,285)

The components of income tax expense are as follows:

	Years Ended December 31,	
	2020	2019
Current:		
Federal	$ —	$ —
State	10,860	3,379
Foreign	3,555	—
Total current income tax expense	$ 14,415	$ 3,379
Deferred:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total deferred income tax expense	$ —	$ —
Total income tax expense	$ 14,415	$ 3,379

The Company's actual income tax expense for the years ended December 31, 2020 and 2019 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,	
	2020	2019
Computed tax (benefit) at 21%	$ (4,379,719)	$ (4,051,800)
State taxes, net of federal benefit	(832,055)	(881,670)
Stock-based compensation	310,811	183,167
Foreign tax rate differential	3,685	4,298
Return to provision	26,120	80,668
Other	31,850	51,737
Research and development tax credit - state	(218,991)	(342,320)
Research and development tax credit - federal	(197,836)	(301,878)
Uncertain tax position adjustment for prior periods	(5,694)	650,687
Increase in valuation allowance	5,276,244	4,610,490
	$ 14,415	$ 3,379

Deferred tax assets and liabilities comprise the following:

	Years Ended December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 43,308,483	$ 38,357,970
Research and development credits	3,475,341	3,061,981
Deferred revenue	50,429	154,497
Inventory reserve	6,653	10,155
Fixed assets and intangibles	313,117	217,332
Accrued NuvoGen liability	1,274,896	1,456,435
Lease liability	269,147	359,603
Other	211,574	150,134
Gross deferred tax assets	48,909,640	43,768,107
Valuation allowance	(48,626,925)	(43,350,682)
Deferred tax assets, net	282,715	417,425
Deferred tax liabilities:		
Right of use asset	257,705	311,633
Other	25,010	105,792
Total deferred tax liabilities	282,715	417,425
Net deferred tax assets (liabilities)	$ -	$ -

As of December 31, 2020, the Company has estimated federal and state net operating loss ("NOL") carryforwards of approximately $177.6 million and $124.5 million for federal and state income tax purposes, respectively, of which $121.8 million are scheduled to expire from 2021 through 2037, while the remaining federal NOLs do not expire. The Company's state NOLs are scheduled to expire from 2027 through 2040. The Company's federal and state tax credit carryforwards begin expiring in 2021.

For financial reporting purposes, valuation allowances of $48.6 million and $43.4 million at December 31, 2020 and 2019, 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 $5.3 million for the year ended December 31, 2020 was primarily due to increased operating losses. The Company has established a valuation allowance against its entire net tax asset. As a result, the Company does not recognize any tax benefit until it is in a taxpaying position or there is no longer negative evidence leading to the conclusion that it is more likely than not that the benefits will not be realized.

Pursuant to Sections 382 and 383 of the IRC, annual use of the Company's NOLs and research and development credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. If limited, the related tax asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. 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. As such, the Company has established a valuation allowance as the realization of its deferred tax assets has not met the more likely than not threshold requirement. Due to the existence of the valuation allowance, further changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

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

	Years Ended December 31,	
	2020	2019
Balance at beginning of year	$ 2,731,015	$ 1,538,220
Increases to prior positions	—	650,687
Decreases to prior positions	(5,694)	—
Increases for current year positions	235,521	542,108
Balance at end of year	$ 2,960,842	$ 2,731,015

As of December 31, 2020, the Company had $3.0 million of gross unrecognized tax benefits, related to research and experimental tax credits. The Company had no unrecognized tax benefits as of December 31, 2020, which, if recognized, would affect the annual effective tax rate, due to the full valuation allowance on the deferred tax assets. Although it is possible that the amount of unrecognized benefits with respect to our uncertain tax positions will increase or decrease in the next twelve months, the Company does not expect material changes.

The CARES Act contains certain income tax relief provisions, including a modification to the limitation of business interest expense for tax years beginning in 2019 and 2020. In addition, the CARES Act permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021, and allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The Company does not anticipate any material impacts to its tax status or reporting as a result of these provisions.

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, 2020, the earliest year subject to examination is 2017 for U.S. federal tax purposes. The earliest year subject to examination is 2016 for the state jurisdictions, and 2019 for France. However, the Company's NOLs and tax credit carryforwards for periods ending December 31, 2001 and thereafter remain subject to examination by the United States and certain states.

Note 17. Subsequent Events

ATM Offering

From January 1 through March 15, 2021, the Company sold approximately 1 million shares of common stock under the ATM Offering at the then-market prices for total gross proceeds of $6.9 million. After sales commissions owed in connection with the ATM Offering, the Company's aggregate net proceeds from sales of common shares under the ATM Offering during this period were $6.7 million.

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, 2020, 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 December 31, 2020, 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 at the reasonable assurance level as of December 31, 2020.

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 the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

The information under Item 2 of Part I of this Annual Report on Form 10-K regarding the amendments to our lease agreements in December 2020 is incorporated by reference under this Item 9B. Copies of the lease amendments are filed with this Annual Report on Form 10-K as Exhibit 10.18 and Exhibit 10.20.

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		
John L. Lubniewski	57	President, Chief Executive Officer and Director
Shaun D. McMeans	59	Senior Vice President, Chief Financial Officer, Treasurer and Secretary
Byron T. Lawson	46	Senior Vice President, Chief Commercial Officer
Non-Employee Directors		
Ann F. Hanham, Ph.D. (3)	68	Chair of Board of Directors
Michelle R. Griffin (1)(2)	55	Director
Harry A. George (1)	72	Director
Donnie M. Hardison (2)	70	Director
James T. LaFrance (1)(3)	62	Director
Lee R. McCracken (2)(3)	63	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and governance committee.

Executive Officers

John L. Lubniewski. Mr. Lubniewski has served as our President and Chief Executive Officer and as a member of our Board of Directors since April 2019 and previously served as our President and Chief Operating Officer since April 2018. Prior to this, he served as our Senior Vice President and Chief Business Officer since April 2011. Mr. Lubniewski joined us from Ventana Medical Systems, Inc. ("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 Holdings, Inc. ("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. Our Board of Directors believes that Mr. Lubniewski's extensive executive management experience in commercialization, marketing, strategic planning and management of operations, as well as his service as our Chief Executive Officer, qualify him to serve on our Board of Directors.

Shaun D. McMeans. Mr. McMeans has served as our Senior Vice President and Chief Financial Officer since February 2018 and as our 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.

Byron T. Lawson. Mr. Lawson has served as our Senior Vice President and Chief Commercial Officer in January 2020 and previously served as our Senior Vice President, Pharma Business Unit since January 2018. Prior to this, he served as our Senior Director, Commercial Options since October 2012. Mr. Lawson joined us from Ventana, where he worked for nearly 15 years and served in a variety of roles with increasingly responsibility in the North American commercial organization. He also served in the United States Air Force for nearly 10 years between Active and Reserve Duty as a certified Histology Technician.

Non-Employee Directors

Ann F. Hanham Ph.D. Dr. Hanham has served on our Board of Directors since August 2016 and as the Chair of our Board of Directors since January 2021. Dr. Hanham also served as the Chair of our Board of Directors from March 2017 to March 2019. From April 2019 to January 2021, Dr. Hanham served as our Lead Independent Director. 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 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 also 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 on our Board of Directors.

Michelle R. Griffin. Ms. Griffin has served on our Board of Directors since August 2018. Ms. Griffin currently serves as a member of the board of directors and chair of the audit committee for Acer Therapeutics, Inc. (Nasdaq: ACER), Adaptive Biotechnologies Corp (Nasdaq: ADPT) and Chinook Therapeutics, Inc. (Nasdaq:KDNY). 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 its 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. (Nasdaq: CRXA) and served as its 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.

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 has served as its Managing General Partner since its formation. Mr. George served as President and CFO of Radiance Therapeutics from June 2018 through September 2020. He has also 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 Radiance Therapeutics, Medipacs, Inc., Post.Bid.Ship, Inc., AdiCyte, Inc., 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 diagnostic company focused on oncology, 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 device company. For more than 20 years prior to that, Mr. Hardison held a number of executive and senior management positions at companies including Laboratory Corporation of America ("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 Stemina Biomarker Discovery, Inc., Seventh Sense Biosystems and IQuity, Inc. He also served on the board of directors of Exact Sciences 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 over thirty-five years of diagnostic industry experience, and has worked since January 2015 as a sales, marketing, strategy development and commercial operational management consultant for LaFrance Consulting LLC, a consulting firm he founded. He currently serves on two additional boards, Aspira Women's Health (Nasdaq: AWH; formerly VRMS) as Chairman; and as an independent director of privately held Personal Genome Diagnostics. He served as interim Chief Executive Officer of Vermillion, Inc. (Nasdaq: VRML) in 2014 and as Chief Executive Officer for Omnyx, LLC, a UPMC/GE Healthcare joint venture from 2012 to 2013. Mr. LaFrance held a series of senior management 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. 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.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. 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. Lubniewski 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. Lubniewski, Mr. George and Mr. Hardison, whose terms will expire at our annual meeting of stockholders to be held in 2023;
- Class II, which consists of Dr. Hanham and Ms. Griffin, whose terms will expire at our annual meeting of stockholders to be held in 2021; and
- Class III, which consists of Mr. McCracken and Mr. LaFrance, whose terms will expire at our annual meeting of stockholders to be held in 2022.

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

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 from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the Board as a whole.

Dr. Hanham serves as Chair of our Board of Directors and Mr. Lubniewski serves as our Chief Executive Officer. Dr. Hanham presides over Board of Directors meetings, sets meeting agendas, ensures the duties, responsibilities and roles of members of our Board of Directors are clearly understood, ensures that our Board of Directors receives appropriate and timely information, material and reports from management regarding our business, provides input to the Board regarding candidates for nomination or appointment to the Board and Board committees, and performs such additional duties as set forth in our bylaws and as our Board of Directors may otherwise determine and delegate.

We also 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 respective committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

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 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 Board committees 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 of Directors 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 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 Ms. Griffin, Mr. Hardison, and Mr. McCracken. 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 2020, 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 2020 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.

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 the Board or any of its directors. Stockholders who wish to communicate with the Board may do so by sending written communications addressed to: Attn: Corporate Secretary, 3430 E. Global Loop, Tucson, Arizona, 85706. These communications will be reviewed by the Secretary, who will determine whether the communication is appropriate for presentation to the Board or the relevant director. The purpose of this screening is to allow the Board 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 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 grants 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, 2020, which consist of our principal executive officer and our two other most highly compensated executive officers as of December 31, 2020, are as follows:

- John L. Lubniewski, our President and Chief Executive Officer;
- Shaun D. McMeans, Senior Vice President and Chief Financial Officer; and
- Byron Lawson, Senior Vice President and Chief Commercial Officer.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Option awards ($) (1)	Non-equity incentive plan compensation ($) (2)	All other compensation ($) (3)	Total ($)
John L. Lubniewski	2020	416,000	930,747	93,600	741	1,441,088
President and Chief Executive Officer	2019	384,125	772,875	—	741	1,157,741
Shaun D. McMeans	2020	358,000	396,744	48,330	741	803,815
Senior Vice President and Chief Financial Officer	2019	320,625	45,125	—	741	366,491
Byron T. Lawson	2020	303,000	182,093	45,450	741	531,284
Chief Commercial Officer	2019	269,875	117,689	60,600	741	448,905

(1) The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2020 and 2019, 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 14 “Stockholders’ Equity” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) Amounts shown represent annual performance-based bonuses earned for 2020 and 2019. The Board of Directors determined that Mr. Lubniewski and Mr. McMeans would forgo a 2019 performance-based bonus.

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

Annual Base Salary

The base salary of our named executive officers is generally set forth in each officer’s employment letter agreement with us and periodically reviewed and adjusted by our Board of Directors, based on the recommendation of our Compensation Committee and following analyses conducted by independent third-party consultants. At the beginning of 2020, the base salaries for our named executive officers were $416,000, $358,000 and $303,000 for Mr. Lubniewski, Mr. McMeans and Mr. Lawson, respectively. In January 2021, the base salaries for Mr. Lubniewski, Mr. McMeans and Mr. Lawson were increased to $460,000, $370,000 and $333,000, 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 2020, Mr. Lubniewski was eligible to receive a target bonus of up to 75% of his base salary pursuant to the terms of his employment letter agreement described below. For 2020, Mr. McMeans was eligible to receive a target bonus of up to 45% of his base salary pursuant to the terms of his employment letter agreement described below. For 2020, Mr. Lawson 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.

The corporate goals established by our Board of Directors for 2020 were based upon financial and strategic goals. Specific goals included direct revenue growth, customer metrics and objectives related to product development. The financial goals and strategic goals were each weighted at 50% 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 2020.

In January 2021, our Board of Directors determined that the 2020 corporate goals had been achieved at an aggregate level of 30%. As a result, our Board of Directors awarded bonuses of $93,600, $48,330 and $45,450 to Mr. Lubniewski, Mr. McMeans and Mr. Lawson, respectively, representing 30% of each executive's target bonus percentage of his base salary for the period.

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, 2020, 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 and 2020 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 and RSU awards vest over a one to four-year period subject to the holder's continuous service to us. Should the Board of Directors deem it appropriate, stock option awards may be granted with an early exercise feature which would allow 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 Mr. Lubniewski. We entered into an amended and restated letter agreement with Mr. Lubniewski in March 2019 that replaced his previous December 2014 letter agreement. The agreement sets forth certain agreed upon terms and conditions of employment. Mr. Lubniewski was initially entitled to receive an annual base salary of $385,000 (which has been increased, most recently in January 2021 to $460,000), an annual target performance bonus of up to 55% of his base salary (increased in January 2020 to 75% of base salary) as determined by the Board of Directors following analysis conducted by independent third-party consultants, and certain severance benefits, which were superseded and replaced by the terms of our Severance Plan, as further 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.

Employment Letter Agreement with Mr. McMeans. We entered into an amended and restated letter agreement with Mr. McMeans in July 2019 that replaced his previous December 2014 letter agreement. 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 January 2021 to $370,000), 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, which were superseded and replaced by the terms of our Severance Plan, as further described below under "—Potential Payments and Benefits upon Termination or Change of Control." Mr. McMeans' base salary and target bonus percentage are subject to modification from time to time in the discretion of our Board of Directors or any authorized committee thereof.

Employment Letter Agreement with Mr. Lawson. We entered into an amended and restated letter agreement with Mr. Lawson in July 2019 that replaced his previous letter agreement and became effective in June 2017. The agreement sets forth certain agreed upon terms and conditions of employment. Mr. Lawson was initially entitled to receive an annual base salary of $250,000 (which has been increased, most recently in January 2021 to $330,000), an annual target performance bonus of up to 40% of his base salary (increased in January 2020 to 50% of base salary) as determined by our Board of Directors, and certain severance benefits, which were superseded and replaced by the terms of our Severance Plan, as further described below under "—Potential Payments and Benefits upon Termination or Change of Control." Mr. Lawson'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.

Potential Payments and Benefits upon Termination or Change of Control

In October 2020, our Compensation Committee adopted our Severance and Change in Control Plan, or the Severance Plan, which provides for severance and/or change in control benefits to our named executive officers upon (i) a "change in control termination" or (ii) a "regular termination" (each as described below). Upon a change in control termination, each of our named executive officers is entitled to receive continued payment of his base salary for a specified period of time (18 months for Mr. Lubniewski, 15 months for Mr. McMeans and 12 months for Mr. Lawson), payment of COBRA premiums for a period of time (up to 18 months for Mr. Lubniewski, 15 months for Mr. McMeans and 12 months for Mr. Lawson) and accelerated vesting of outstanding time-vesting equity awards. Upon a regular termination, each of our named executive officers is entitled to receive continued payment of his base salary for a specified period of time (12 months for Mr. Lubniewski, 12 months for Mr. McMeans and 9 months for Mr. Lawson) and payment of COBRA premiums for a period of time (up to 12 months for Mr. Lubniewski, 12 months for Mr. McMeans and 9 months for Mr. Lawson). All severance benefits under the Severance Plan are subject to the executive's execution of an effective release of claims against the Company. The Severance Plan superseded and replaced any change in control or severance benefit plans previously provided to our named executive officers, including any such benefits in their amended and restated letter agreements with us.

For purposes of the Severance Plan, a "regular termination" is an involuntary termination (i.e., a termination other than for cause (and not as a result of death or disability) or a resignation for good reason, as defined in the Severance Plan) that does not occur during the period of time beginning three months prior to, and ending 12 months following, a "change in control" (as defined in the 2020 Plan), or the "change in control period." A "change in control termination" is a regular termination that occurs during the change in control period.

For purposes of the Severance Plan, "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 the Severance Plan, "good reason" generally means the following undertaken by us with respect to the executive without the executive's prior 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 (which, with respect to Mr. Lubniewski, includes a change requiring him to report to a corporate officer or employee rather than directly to the Board of Directors); (4) a material breach by the Company of any provision of the Severance Plan or any other material agreement between the executive and the Company concerning the terms and conditions of the executive's employment; or (5) 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, 2020, granted under the 2001 Plan, the 2011 Plan, the 2014 Plan and the 2020 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	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
John L. Lubniewski	4/26/2011	869	—	32.25	4/26/2021	—	—
	3/08/2012	186	—	32.25	3/08/2022	—	—
	2/01/2013	233	—	32.25	2/01/2023	—	—
	8/06/2013	869	—	32.25	8/06/2023	—	—
	3/20/2014	1,987	—	32.25	3/20/2024	—	—
	12/29/2014	248	—	193.35	12/29/2024	—	—
	2/16/2016	2,333	—	35.40	2/15/2026	—	—
	2/13/2017	1,333	—	28.80	2/13/2027	—	—
(1)	8/16/2018	4,170	2,496	51.00	8/16/2028	—	—
(2)	5/23/2019	12,915	7,085	33.30	5/23/2029	—	—
(3)	8/15/2019	5,004	2,496	14.25	8/15/2029	—	—
(2)	1/23/2020	17,916	17,917	9.90	1/23/2030	—	—
(1)	8/20/2020	8,362	71,638	7.20	8/20/2030	—	—
(4)	8/16/2018	—	—			1,248	63,648
Shaun D. McMeans	3/08/2012	558	—	32.25	3/08/2022	—	—
	2/01/2013	123	—	32.25	2/01/2023	—	—
	8/06/2013	869	—	32.25	8/06/2023	—	—
	3/20/2014	2,020	—	32.25	3/20/2024	—	—
	12/29/2014	155	—	193.35	12/29/2024	—	—
	2/16/2016	1,333	—	35.40	2/15/2026	—	—
	2/13/2017	1,233	—	28.80	2/13/2027	—	—
(1)	8/16/2018	4,170	2,496	51.00	8/16/2028	—	—
(3)	8/15/2019	2,118	1,048	14.25	8/15/2029	—	—
(2)	1/23/2020	7,920	7,913	9.90	1/23/2030	—	—
(1)	8/20/2020	3,491	29,842	7.20	8/20/2030	—	—
(4)	8/16/2018	—	—			622	31,722
Byron T. Lawson	10/3/2012	62	—	32.25	10/3/2022		
	2/1/2013	13	—	32.25	2/1/2023		
	8/6/2013	124	—	32.25	8/6/2023		
	3/20/2014	350	—	32.25	3/20/2024		
	12/29/2014	124	—	193.35	12/29/2024		
	11/25/2015	666	—	76.20	11/25/2025		
	5/25/2016	333	—	42.25	5/25/2026		
	1/31/2017	666	—	26.25	1/31/2027		
(1)	5/31/2017	294	39	51.90	5/31/2027		
	7/25/2017	500	—	35.85	7/25/2027		
(1)	8/16/2018	1,250	750	51.00	8/16/2028		
(3)	8/6/2019	2,894	1,439	20.70	8/6/2029		
(3)	9/12/2019	1,553	780	12.00	9/12/2029		
(2)	1/7/2020	2,328	2,338	11.25	1/7/2030		
(3)	8/20/2020	1,918	16,082	7.20	8/20/2030		
(4)	8/16/2018	—	—			503	25,653

(1) Stock options vest over four years as follows: 1/16th 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.

(2) Stock options vest at the end of each month beginning January 30, 2020, with 50% vesting in the first year and 25% vesting in each of years 2 and 3, subject to the individual's continued service with us through each vesting date.

(3) Stock options vest in equal monthly installments over a two-year period, subject to the individual's continued service with us through each vesting date.

(4) RSUs vest over four years as follows: 1/16th 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

2020 Equity Incentive Plan

In August 2020, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the 2020 Equity Incentive Plan (the "2020 Plan") as a successor to and continuation of the 2014 Plan. As of December 31, 2020, option awards covering an aggregate of 256,602 shares of our common stock and an additional 5,156 RSU awards granted under the 2020 Plan were outstanding.

Stock Awards. The 2020 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 awards and other awards.

Share Reserve. Subject to adjustment for certain changes in our capitalization, the aggregate number of shares of our common stock that may be issued under the 2020 Plan will not exceed 744,685 shares, which number is the sum of (i) the number of shares remaining available for the grant of new awards under the 2014 Plan (excluding shares available for the grant of inducement awards under the 2014 Plan's inducement share pool) as of immediately prior to the effective date of the 2020 Plan; (ii) 676,133 new shares; and (iii) the number of the Prior Plan Returning Shares (as defined below), if any, as such shares become available from time to time.

The "Prior Plan Returning Shares" are shares of our common stock subject to outstanding awards granted under the 2014 Plan (excluding shares available for the granting of inducement awards under the 2014 Plan), the 2011 Plan or 2001 Plan (together, the "Prior Plans," and each such award, a "Prior Plan Award") that, following the effective date of the 2020 Plan: (i) are not issued because such award or any portion thereof expires or otherwise terminates without all of the shares covered by such award having been issued; (ii) are not issued because such award or any portion thereof is settled in cash; or (iii) are forfeited back to or repurchased by us because of the failure to meet a contingency or condition required for the vesting of such shares. The number of shares of our common stock available for issuance under the 2020 Plan will be reduced or increased by (i) one share for each share of common stock issued pursuant to an Appreciation Award (as defined in the 2020 Plan), and (ii) 1.5 shares for each share of common stock issued pursuant to a Full Value Award (as defined in the 2020 Plan). The following actions will not result in an issuance of shares of our common stock under the 2020 Plan and accordingly will not reduce the number of shares of our common stock available for issuance under the 2020 Plan: (i) the expiration or termination of any portion of an award granted under the 2020 Plan without the shares covered by such portion of the award having been issued; or (ii) the settlement of any portion of an award granted under the 2020 Plan in cash.

If any shares of our common stock issued pursuant to an award granted under the 2020 Plan are forfeited back to or redeemed or repurchased by us because of the failure to meet a contingency or condition required for the vesting of such shares, then such shares will become available again for issuance under the 2020 Plan.

The following shares of our common stock will not become available again for issuance under the 2020 Plan: (i) any shares that are reacquired or withheld (or not issued) by us to satisfy the exercise or strike price of an award granted under the 2020 Plan or a Prior Plan Award (including any shares subject to such award that are not delivered because such award is exercised through a reduction of shares subject to such award); (ii) any shares that are reacquired or withheld (or not issued) by us to satisfy a tax withholding obligation in connection with an award granted under the 2020 Plan or a Prior Plan Award; (iii) any shares repurchased by us on the open market with the proceeds of the exercise or strike price of an award granted under the 2020 Plan or a Prior Plan Award; and (iv) in the event that a stock appreciation right granted under the 2020 Plan or a stock appreciation right that is a Prior Plan Award is settled in shares, the gross number of shares subject to such award.

Eligibility. All of our (including our affiliates') employees, non-employee directors and consultants are eligible to participate in the 2020 Plan and may receive all types of awards other than incentive stock options. Incentive stock options may be granted under the 2020 Plan only to our (including our affiliates') employees.

Administration. The 2020 Plan will be administered by our Board of Directors, which may in turn delegate some or all of the administration of the 2020 Plan to a committee or committees composed of members of the board of directors. Our Board of Directors has delegated concurrent authority to administer the 2020 Plan to our Compensation Committee, but may, at any time, revest in itself some or all of the power delegated to our Compensation Committee. We refer to the plan administrator as the "Plan Administrator" herein.

Subject to the terms of the 2020 Plan, the Plan Administrator may determine the recipients, the types of awards to be granted, the number of shares of our common stock subject to or the cash value of awards, and the terms and conditions of awards granted under the 2020 Plan, including the period of their exercisability and vesting. The Plan Administrator has the authority to provide for accelerated exercisability and vesting of awards. Subject to the limitations set forth below, the Plan Administrator also determines the fair market value applicable to an award and the exercise or strike price of stock options and stock appreciation rights granted under the 2020 Plan.

In addition, the Plan Administrator may delegate to one or more executive officers the authority to designate employees who are not executive officers to be recipients of certain awards and the number of shares of our common stock subject to such awards. Under any such delegation, the Plan Administrator will specify the total number of shares of our common stock that may be subject to the awards granted by such executive officer. The executive officer may not grant an award to himself or herself.

Repricing; Cancellation and Re-Grant of Stock Options or Stock Appreciation Rights. Under the 2020 Plan, unless our stockholders have approved such an action within 12 months prior to such an event, the Plan Administrator does not have the authority to reprice any outstanding stock option or stock appreciation right by (1) reducing the exercise or strike price of the stock option or stock appreciation right, or (2) canceling any outstanding stock option or stock appreciation right that has an exercise or strike price greater than the then-current fair market value of our common stock in exchange for cash or other awards.

Limit on Non-Employee Director Compensation. Pursuant to the 2020 Plan, the aggregate value of all compensation granted or paid, as applicable, by the Company to any individual for service as a non-employee director with respect to any period commencing on the date of the annual meeting of stockholders for a particular year and ending on the day immediately prior to the date of the annual meeting of stockholders for the next subsequent year (the "Annual Period"), including awards granted and cash fees paid by the Company to such non-employee director, will not exceed (i) $400,000 in total value or (ii) in the event such non-employee director is first appointed or elected to the Board of Directors during such Annual Period, $600,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes.

Dividends and Dividend Equivalents. The 2020 Plan provides that dividends or dividend equivalents may be paid or credited with respect to any shares of our common stock subject to an award other than an option or stock appreciation right, as determined by the Plan Administrator and contained in the applicable award agreement; *provided, however,* that (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be subject to all of the terms and conditions applicable to such shares under the terms of the applicable award agreement (including any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to us on the date such shares are forfeited to or repurchased by us due to a failure to vest.

Stock Options. Stock options may be granted under the 2020 Plan pursuant to stock option agreements. The 2020 Plan permits the grant of stock options that are intended to qualify as ISOs and NSOs.

The exercise price of a stock option granted under the 2020 Plan may not be less than 100% of the fair market value of the common stock subject to the stock option on the date of grant and, in some cases (see "-Limitations on Incentive Stock Options" below), may not be less than 110% of such fair market value.

The term of stock options granted under the 2020 Plan may not exceed ten years from the date of grant and, in some cases (see "-Limitations on Incentive Stock Options" below), may not exceed five years from the date of grant. Except as otherwise provided in a participant's stock option agreement or other written agreement with us or one of our affiliates, if a participant's service relationship with us or any of our affiliates ("continuous service" as defined in the 2020 Plan) terminates (other than for cause (as defined in the 2020 Plan) or the participant's death or disability (as defined in the 2020 Plan)), the participant may exercise any vested stock options for up to three months following the participant's termination of continuous service. Except as otherwise provided in a participant's stock option agreement or other written agreement with us or one of our affiliates, if a participant's continuous service terminates due to the participant's disability, the participant may exercise any vested stock options for up to 12 months following the participant's termination due to the participant's disability. Except as otherwise provided in a participant's stock option agreement or other written agreement with us or one of our affiliates, if a participant's continuous service terminates due to the participant's death (or the participant dies within a specified period following termination of continuous service), the participant's beneficiary may exercise any vested stock options for up to 18 months following the participant's death. Except as explicitly provided otherwise in a

participant's stock option agreement or other written agreement with us or one of our affiliates, if a participant's continuous service is terminated for cause, all stock options held by the participant will terminate upon the participant's termination of continuous service and the participant will be prohibited from exercising any stock option from and after such termination date. Except as otherwise provided in a participant's stock option agreement or other written agreement with us or one of our affiliates, the term of a stock option may be extended if a participant's continuous service terminates for any reason other than for cause and, at any time during the applicable post-termination exercise period, the exercise of the stock option would be prohibited by applicable laws or the sale of any common stock received upon such exercise would violate our insider trading policy. In no event, however, may a stock option be exercised after its original expiration date.

Acceptable forms of consideration for the purchase of our common stock pursuant to the exercise of a stock option under the 2020 Plan will be determined by the Plan Administrator and may include payment: (i) by cash, check, bank draft or money order payable to us; (ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board; (iii) by delivery to us of shares of our common stock (either by actual delivery or attestation); (iv) by a net exercise arrangement (for NSOs only); or (v) in other legal consideration approved by the Plan Administrator.

Stock options granted under the 2020 Plan may become exercisable in cumulative increments, or "vest," as determined by the Plan Administrator at the rate specified in the stock option agreement. Shares covered by different stock options granted under the 2020 Plan may be subject to different vesting schedules as the Plan Administrator may determine.

The Plan Administrator may impose limitations on the transferability of stock options granted under the 2020 Plan in its discretion. Generally, a participant may not transfer a stock option granted under the 2020 Plan other than by will or the laws of descent and distribution or, subject to approval by the Plan Administrator, pursuant to a domestic relations order. However, the Plan Administrator may permit transfer of a stock option in a manner that is not prohibited by applicable tax and securities laws. Options may not be transferred to a third-party financial institution for value.

Limitations on Incentive Stock Options. In accordance with current federal tax laws, the aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to ISOs that are exercisable for the first time by a participant during any calendar year under all of our stock plans may not exceed $100,000. The stock options or portions of stock options that exceed this limit or otherwise fail to qualify as ISOs are treated as NSOs. No ISO may be granted to any person who, at the time of grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power unless the following conditions are satisfied:

- the exercise price of the ISO must be at least 110% of the fair market value of the common stock subject to the ISO on the date of grant; and
- the term of the ISO must not exceed five years from the date of grant.

Subject to adjustment for certain changes in our capitalization, the aggregate maximum number of shares of our common stock that may be issued pursuant to the exercise of ISOs under the 2020 Plan is 1,495,097 shares.

Stock Appreciation Rights. Stock appreciation rights may be granted under the 2020 Plan pursuant to stock appreciation right agreements. Each stock appreciation right is denominated in common stock share equivalents. The strike price of each stock appreciation right will be determined by the Plan Administrator but will in no event be less than 100% of the fair market value of the common stock subject to the stock appreciation right on the date of grant. The term of stock appreciation rights granted under the 2020 Plan may not exceed ten years from the date of grant. The Plan Administrator may also impose restrictions or conditions upon the vesting of stock appreciation rights that it deems appropriate. The appreciation distribution payable upon exercise of a stock appreciation right may be paid in shares of our common stock, in cash, in a combination of cash and stock, or in any other form of consideration determined by the Plan Administrator and set forth in the stock appreciation right agreement. Stock appreciation rights will be subject to the same conditions upon termination of continuous service and restrictions on transfer as stock options under the 2020 Plan.

Restricted Stock Awards. Restricted stock awards may be granted under the 2020 Plan pursuant to restricted stock award agreements. A restricted stock award may be granted in consideration for cash, check, bank draft or money order payable to us, the participant's services performed for us, or any other form of legal consideration acceptable to the Plan Administrator. Shares of our common stock acquired under a restricted stock award may be subject to forfeiture to or repurchase by us in accordance with a vesting schedule to be determined by the Plan Administrator. Rights to acquire shares of our common stock under a restricted stock award may be transferred only upon such terms and conditions as are set forth in the restricted stock award agreement. Upon a participant's termination of continuous service for any reason, any shares subject to restricted stock awards held by the participant that have not vested as of such termination date may be forfeited to or repurchased by us.

Restricted Stock Unit Awards. Restricted stock unit awards may be granted under the 2020 Plan pursuant to restricted stock unit award agreements. Payment of any purchase price may be made in any form of legal consideration acceptable to the Plan Administrator. A restricted stock unit award may be settled by the delivery of shares of our common stock, in cash, in a combination of cash and stock, or in any other form of consideration determined by the Plan Administrator and set forth in the restricted stock unit award agreement. Restricted stock unit awards may be subject to vesting in accordance with a vesting schedule to be determined by the Plan Administrator. Except as otherwise provided in a participant's restricted stock unit award agreement or other written agreement with us, restricted stock units that have not vested will be forfeited upon the participant's termination of continuous service for any reason.

Performance Awards. The 2020 Plan allows us to grant performance awards. A performance award is an award that may vest or may be exercised, or that may become earned and paid, contingent upon the attainment of certain performance goals during a performance period. A performance award may require the completion of a specified period of continuous service. The length of any performance period, the performance goals to be achieved during the performance period, and the measure of whether and to what degree such performance goals have been attained will be determined by the Plan Administrator in its discretion. In addition, to the extent permitted by applicable law and the applicable award agreement, the Plan Administrator may determine that cash may be used in payment of performance awards.

Performance goals under the 2020 Plan will be established by the board of directors for a performance period. The performance criteria used to establish such goals may be based on any measure of performance selected by the board of directors.

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 by the Plan Administrator (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 performance goals are established, the Plan Administrator will appropriately make adjustments in the method of calculating the attainment of the performance goals for a performance period 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 items that are "unusual" in nature or occur "infrequently" 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 the Company 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 common stock of the Company 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 the Company's 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 U.S. Food and Drug Administration or any other regulatory body.

In addition, the Plan Administrator retains the discretion to define the manner of calculating the performance criteria it selects to use for a performance period and to reduce, increase or eliminate the compensation or economic benefit due upon the attainment of any performance goal.

Other Awards. Other forms of awards valued in whole or in part by reference to, or otherwise based on, our common stock, may be granted either alone or in addition to other awards under the 2020 Plan; provided that any such award will be treated as a Full Value Award. Subject to the terms of the 2020 Plan, the Plan Administrator will have sole and complete authority to determine the persons to whom and the time or times at which such other awards will be granted, the number of shares of our common stock to be granted and all other terms and conditions of such other awards.

Clawback Policy. Awards granted under the 2020 Plan will be subject to recoupment in accordance with any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law, and any other clawback policy that the Company adopts. In addition, the board of directors may impose such other clawback, recovery or recoupment provisions in an award agreement as the board of directors determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of common stock or other cash or property upon the occurrence of cause.

Changes to Capital Structure. In the event of certain capitalization adjustments, the Plan Administrator will appropriately and proportionately adjust: (i) the class(es) and maximum number of shares of our common stock subject to the 2020 Plan; (ii) the class(es) and maximum number of shares of our common stock that may be issued pursuant to the exercise of ISOs; and (iii) the class(es) and number of shares of our common stock and the exercise, strike or purchase price per share of our common stock subject to outstanding awards.

Corporate Transaction and Change in Control. The following applies to each outstanding award under the 2020 Plan in the event of a corporate transaction (as defined in the 2020 Plan and described below) or a change in control (as defined in the 2020 Plan and described below), unless provided otherwise in the applicable award agreement or in any other written agreement between a participant and the Company or an affiliate. The term "Transaction" will mean such corporate transaction or change in control.

In the event of a Transaction, any awards outstanding under the 2020 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company) (such entity, the "acquiring entity"), and any reacquisition or repurchase rights held by us with respect to the award may be assigned to the acquiring entity. If the acquiring entity does not assume, continue or substitute for such awards, then with respect to any such awards that are held by participants whose continuous service has not terminated prior to the effective time of the Transaction (such participants, the "current participants"), the vesting (and exercisability, if applicable) of such awards will be accelerated in full to a date prior to the effective time of the Transaction (contingent upon the effectiveness of the Transaction), and such awards will terminate if not exercised (if applicable) at or prior to the effective time of the Transaction, and any reacquisition or repurchase rights held by us with respect to such awards will lapse (contingent upon the effectiveness of the Transaction). With respect to the vesting of performance awards that will accelerate upon the occurrence of a Transaction, unless otherwise provided in the relevant award agreement, the vesting of such performance awards will accelerate at 100% of the target level upon the occurrence of the Transaction. If the acquiring entity does not assume, continue or substitute for such awards, then any such awards that are held by persons other than current participants will terminate if not exercised (if applicable) at or prior to the effective time of the Transaction, except that any reacquisition or repurchase rights held by us with respect to such awards will not terminate and may continue to be exercised notwithstanding the Transaction.

In the event an award will terminate if not exercised at or prior to the effective time of a Transaction, the Plan Administrator may provide that the holder of such award may not exercise such award but instead will receive a payment equal in value to the excess, if any, of (i) the value of the property the participant would have received upon the exercise of the award, over (ii) any exercise price payable by such holder in connection with such exercise.

Under the 2020 Plan, a "corporate transaction" generally means the consummation of any one or more of the following events: (1) a sale or other disposition of all or substantially all of our assets; (2) a sale or other disposition of at least 50% of our outstanding securities; (3) a merger, consolidation or similar transaction where we do not survive the transaction; or (4) a merger, consolidation or similar transaction where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Under the 2020 Plan, a "change in control" generally means the occurrence of any one or more of the following events: (1) the acquisition by any person, entity or group of our securities representing more than 50% of the combined voting power of our then outstanding securities, other than by virtue of a merger, consolidation, or similar transaction; (2) a consummated merger, consolidation or similar transaction in which our stockholders immediately before such transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; or (3) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets, other than to an entity, more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction.

Plan Amendments and Termination. The Plan Administrator will have the authority to amend or terminate the 2020 Plan at any time. However, except as otherwise provided in the 2020 Plan, no amendment or termination of the 2020 Plan may materially impair a participant's rights under his or her outstanding awards without the participant's consent. We will obtain stockholder approval of any amendment to the 2020 Plan as required by applicable law and listing requirements.

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. In August 2020, upon the effective date of the 2020 Plan, the 2014 Plan ceased to be available for new grants of equity awards, and any shares remaining available for issuance under the 2014 Plan (excluding shares available for the granting of inducement awards under the 2014 Plan's inducement share pool) became available for issuance under the 2020 Plan.

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) 61,707 shares, plus (2) the number of shares (not to exceed 40,587 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 increased on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2020, 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 120,000 shares.

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.

In May 2019, 13,333 shares were reserved for issuance under the 2014 Plan pursuant to an amendment approved by our Board of Directors pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules, to be used exclusively for the grant of awards to individuals who were not previously employees or non-employee directors of the Company, as inducement material to the individuals' entering into employment ("Inducement Awards").

As of December 31, 2020, option awards covering an aggregate of 210,935 shares of our common stock, including 2,332 inducement awards, and an additional 7,058 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. 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 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.

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, 2020, option awards under the 2011 Plan covering an aggregate of 19,617 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 2020 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, 2020, option awards under the 2001 Plan covering an aggregate of 73 shares of our common stock were outstanding.

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 7,388 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) 13,000 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 2020, 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, 2020 to each of our non-employee directors as well as our former Executive Chairman:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Ann F. Hanham	74,038	27,600	101,638
Michelle R. Griffin	56,000	27,600	83,600
Harry A. George	42,500	27,600	70,100
Donnie M. Hardison	47,000	27,600	74,600
James T. LaFrance	47,019	27,600	74,619
Lee R. McCracken	45,519	27,600	73,119
Timothy B. Johnson	100,000	28,800	128,800

(1) As of December 31, 2020, the aggregate number of outstanding options to purchase our common stock held by our non-employee directors were: Dr. Hanham: 6,398, Ms. Griffin: 5,999, Mr. George: 6,532; Mr. Hardison: 6,798; Mr. LaFrance: 6,798; Mr. McCracken: 6,798; and Mr. Johnson 32,975, in addition to 2,187 outstanding RSU awards. The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2020. 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 14 “Stockholders’ Equity” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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, 2020:

- 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, $12,000 and $8,000 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, $6,000 and $4,000 for service as member of our Audit Committee, Compensation Committee and Nominating and Governance Committee, respectively;
- an automatic annual option grant to purchase 666 shares of our common stock and an automatic RSU award for 166 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 1,666 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 June 2020, 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, $12,000 and $10,000 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, $6,000 and $5,000 for service as member of our Audit Committee, Compensation Committee and Nominating and Governance Committee, respectively;
- an automatic annual option grant to purchase 4,000 shares of our common stock for each non-employee director who is serving on our 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 8,000 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 2020 Plan. The stock options will be granted under the 2020 Plan, the terms of which are described in more detail above under "– Equity Benefit Plans – 2020 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, 2020.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders:			
2001 Stock Option Plan	73	$ 64.50	—
2011 Equity Incentive Plan	19,617	45.74	—
2014 Equity Incentive Plan (1) (2)	215,661	26.64	—
2014 Employee Stock Purchase Plan (3)	—	N/A	24,922
2020 Equity Incentive Plan	261,758	7.04	513,619
Equity compensation plans not approved by security holders (4)	2,332	14.25	—
Total	499,441		538,541

(1) On January 1 of each year from January 1, 2016 through and including January 1, 2020, the number of shares authorized for issuance under the 2014 Plan was 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, 2020, the available shares for purchase under the 2014 Plan was increased by 154,907 shares. Upon adoption of the 2020 Plan in August 2020, there will no longer be an annual authorized share increase.

(2) The number of shares to be issued upon exercise of outstanding options, RSUs, warrants and rights under the 2014 Equity Incentive Plan includes 7,058 outstanding RSU awards. The number of shares to be issued upon exercise of outstanding options, RSUs, warrants and rights under the 2020 Plan includes 5,156 outstanding RSU awards. These shares have been excluded from weighted-average exercise price in column (b) above.

(3) 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) 13,000 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, 2020, the available shares for purchase under our ESPP was increased by 13,000 shares.

(4) In May 2019, 13,333 shares of our common stock were reserved for issuance under the 2014 Equity Incentive Plan pursuant to an amendment approved by our Board of Directors pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules, to be used exclusively for the grant of awards to individuals who were not previously employees or non-employee directors, as inducement

material to the individuals' entering into employment with us. As of December 31, 2020, there were no Inducement Awards available for issuance.

Principal Stockholders

The following table sets forth certain information regarding the ownership of the Company's common stock as of February 26, 2021 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 6,104,331 shares outstanding on February 26, 2021, 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		
Laurence W. Lytton (1)	484,412	7.9%
467 Central Park West		
New York, NY 10025		
Cowen Prime Advisors (2)	441,918	7.2%
599 Lexington Avenue, Floor 21		
New York, NY 10022		
Nantahala Capital Management, LLC (3)	363,622	6.0%
130 Main Street 2nd Floor		
New Canaan, CT 06840		
Samjo Capital, LLC, Samjo Management, LLC and Andrew N. Wiener (4)	381,713	6.3%
1345 Avenue of the Americas, 3rd Floor		
New York, NY 10105		
Directors and named executive officers		
John L. Lubniewski (5)	81,859	1.3%
Shaun D. McMeans (6)	37,601	*
Byron Lawson (7)	19,115	*
Ann Hanham (8)	2,884	*
Harry A. George (9)	14,757	*
Michelle R. Griffin (10)	1,943	*
Donnie M. Hardison (11)	3,631	*
James T. LaFrance (12)	3,631	*
Lee McCracken (13)	3,131	*
All current executive officers and directors as a group (9 persons) (14)	168,552	**2.7%**

* Represents beneficial ownership of less than one percent.

(1) Laurence W. Lytton may be deemed to be the beneficial owner of 484,412 shares of the Company's common stock. This information is based on the Schedule 13G filed on February 16, 2021 with the SEC.

(2) Cowen Prime Advisors ("CPA"), a division of Cowen Prime Services LLC Cowen Prime Advisors ("CPA"), a division of Cowen Prime Services LLC ("CPS") is a registered investment adviser under the Investment Advisers Act of 1940. CPS is also registered as a broker-dealer with the SEC, as an Introducing Broker with the CFTC, a member of FINRA and a member of NFA. In its role as investment adviser, CPA possesses discretionary investment authority to determine the identity and amount of securities to be bought and sold, including 441,918 shares of the Company's common stock. These securities are owned by various clients, who have retained sole proxy voting authority over all of the shares. However, CPA has sole authority to dispose of the position as appropriate. CPA reported the total number of shares beneficially owned by CPA as discretionary investment manager in the Information Table filed by CPA as part of its fourth quarter 2020 Form 13F filing. Andrew N. Wiener, one of the portfolio managers of the CPA Samjo Investment Program ("SI"), is also the sole Managing Member of Samjo Capital, LLC and Samjo Management, LLC which serve as the General Partner and Management Company, respectively, of Samjo Partners, LP, an investment partnership (hedge fund) and HAFF Partners LP, a family investment partnership, both of which employ investment strategies that are similar to those employed in the CPA SI program. Samjo Capital, LLC, Samjo Management, LLC, Samjo Partners, LP and HAFF Partners LP are not affiliated with CPA. Mr. Wiener, along with his fellow CPA SI portfolio managers identified below, is responsible for the decision to invest client accounts of CPA SI in shares of this issuer. In addition to Mr. Wiener's portfolio management responsibilities for CPA SI, Mr. Wiener may invest, and from time to time has, invested assets of his non-CPA clients in shares of this same issuer. However, because these non-CPA clients are an unaffiliated outside business activity of Mr. Wiener over which CPA has no control or other relationship, CPA does not make joint filings with respect to any shares of the issuer held by any non-CPA clients. To the best of CPA's knowledge and belief, Mr. Wiener reports the ownership of shares by such non-CPA clients separately to the extent required and is identified as the reporting person. This information is based on the Schedule 13G filed on February 4, 2020 with the SEC and the Schedule 13G-HR filed on January 27, 2021 with the SEC.

(3) Nantahala Capital Management, LLC may be deemed to be the beneficial owner of 363,622 shares of Company's common stock held by funds and separately managed accounts under its control, and as the managing members of Nantahala Capital Management, LLC, each of Wilmot B. Harkey and Daniel Mack may be deemed to be a beneficial owner of these shares. This information is based on the Schedule 13G filed on February 16, 2021 with the SEC.

(4) Samjo Capital, LLC and Samjo Management, LLC, Delaware limited liability companies and Andrew N. Wiener, as sole managing member of these entities have reported shared voting power over 381,713 shares of the Company's common stock. This information is based on the Schedule 13G filed on February 11, 2021 with the SEC.

(5) Includes 72,603 shares that Mr. Lubniewski has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options and the vesting of RSUs.

(6) Includes 30,452 shares that Mr. McMeans has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options and the vesting of RSUs.

(7) Includes 16,689 shares that Mr. Lawson has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options and the vesting of RSUs.

(8) Includes 2,398 shares that Dr. Hanham has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options.

(9) Consists of (i) 9,624 shares beneficially owned by Solstice Capital II LP and (ii) 2,532 shares that Mr. George has the right to acquire from us within 60 days of February 28, 2020 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.

(10) Includes 1,777 shares that Ms. Griffin has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options.

(11) Includes 2,798 shares that Mr. Hardison has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options.

(12) Includes 2,798 shares that Mr. LaFrance has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options.

(13) Includes 2,798 shares that Mr. McCracken has the right to acquire from us within 60 days of February 28, 2020 pursuant to the exercise of stock options.

(14) The number of shares beneficially owned consists of (a) the shares described in Notes (5) through (13).

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, 2019 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."

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. Lubniewski 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 2020 and 2019.

	December 31,	
	2020	2019
Fee Category		
Audit fees (1)	$ 501,000	$ 581,796
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total fees	$ 501,000	$ 581,796

(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 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, LLC, 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	Certificate of Amendment to 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 November 19, 2020).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 0001-37369), filed with the SEC on February 26, 2020).
3.4	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, 3.2, 3.3 and 3.4
4.2	Form of Common Stock Certificate of the Registrant.
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).
4.10	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 (File No. 001-37369), filed with the SEC on May 10, 2018).
4.11	Form of Pre-Funded Warrant to Purchase Shares of Common Stock, dated September 24, 2019 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 23, 2019).
4.12	Warrant to Purchase Common Stock, issued to Silicon Valley Bank on June 24, 2020 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 25, 2020).

Exhibit Number	Description
4.13	Description of Capital Stock
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
10.2+	HTG Molecular Diagnostics, Inc. 2001 Stock Option Plan and Forms of Stock Option Agreement and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
10.3+	HTG Molecular Diagnostics, Inc. 2011 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201313), originally filed with the SEC on December 30, 2014).
10.4+	HTG Molecular Diagnostics, Inc. 2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on May 9, 2019).
10.5+	Standard Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the HTG Molecular Diagnostics, Inc. 2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on May 9, 2019).
10.6+	Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice for Inducement Award Recipients under the HTG Molecular Diagnostics, Inc. 2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37369), filed with the SEC on May 9, 2019).
10.7+	HTG Molecular Diagnostics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 0001-37369), filed with the Commission on August 20, 2020).
10.8+	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the HTG Molecular Diagnostics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-248207), filed with the Commission on August 20, 2020).
10.9+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the HTG Molecular Diagnostics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-248207), filed with the Commission on August 20, 2020).
10.10+	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).
10.11	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 (File No. 001-37369), filed with the SEC on August 9, 2016).
10.12+	HTG Molecular Diagnostics, Inc. Amended and Restated Non-Employee Director Compensation Policy.
10.13+	HTG Molecular Diagnostics, Inc. Severance and Change in Control Plan.
10.14+	Employment Agreement, dated April 1, 2019, by and between John L. Lubniewski and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 2, 2019).
10.15+	Employment Agreement, dated July 28, 2019, by and between Shaun D. McMeans and the Registrant (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 12, 2019).
10.16+	Employment Agreement, dated July 28, 2019, by and between Byron Lawson and the Registrant (incorporated by reference to Exhibit 10.47 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 25, 2020).

Exhibit Number	Description
10.17*	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).
10.18	Second Amendment to Lease Agreement (Suite 300 – Laboratory), dated December 8, 2020, by and between the Registrant and Pegasus Properties, L.P.
10.19	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 (incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 7, 2019).
10.20	Third Amendment to Lease Agreement (Suite 100 – Administration), dated December 8, 2020, by and between the Registrant and Pegasus Properties, L.P.
10.21	Controlled Equity Offering℠ Sales Agreement, dated as of November 14, 2019, by and between HTG Molecular Diagnostics, Inc. and Cantor Fitzgerald & Co (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 15, 2019).
10.22	Loan and Security Agreement dated June 24, 2020, by and among the Registrant and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the SEC on June 24, 2020).
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 received 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.

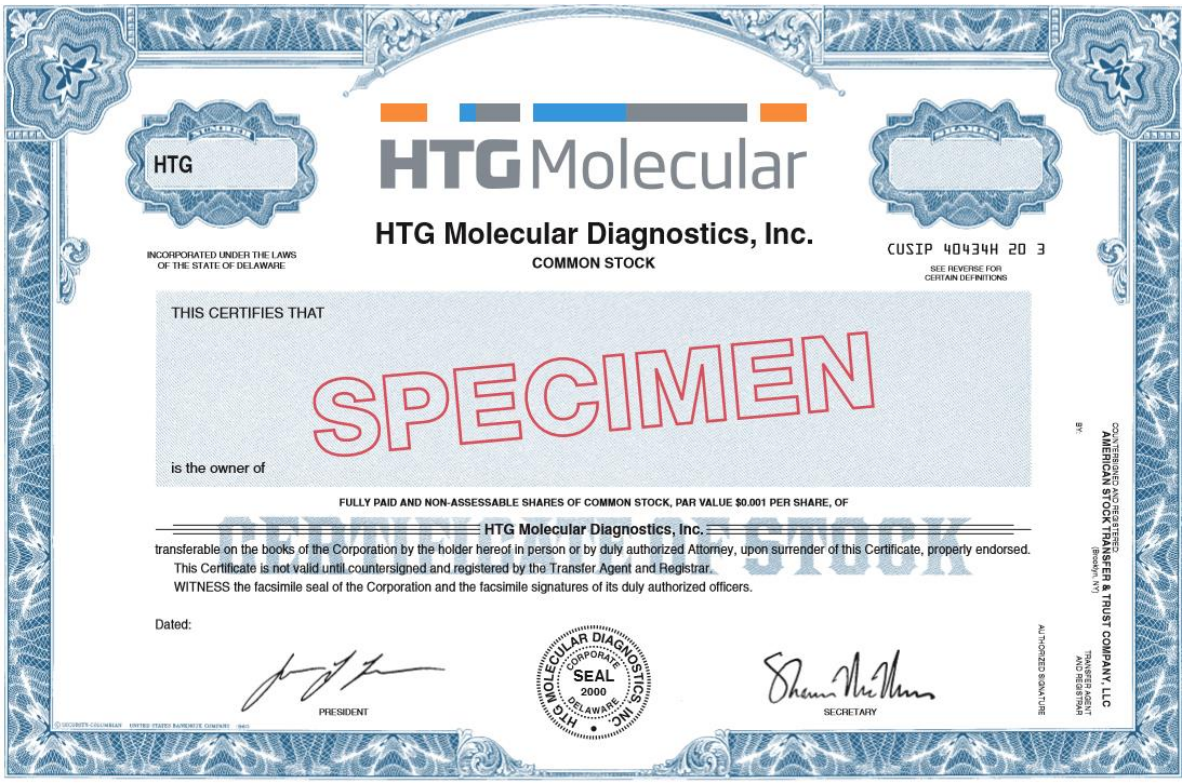
Date: March 25, 2021

By: /s/ John L. Lubniewski
John L. Lubniewski
Chief Executive Officer
(Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John L. Lubniewski 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/ John L. Lubniewski John L. Lubniewski	President and Chief Executive Officer and Director	March 25, 2021
/s/ Shaun D. McMeans Shaun D. McMeans	Senior Vice President and Chief Financial Officer	March 25, 2021
/s/ Laura L. Godlewski Laura L. Godlewski	Vice President of Finance and Principal Accounting Officer	March 25, 2021
/s/ Ann F. Hanham Ann F. Hanham	Chair of Board of Directors	March 25, 2021
/s/ Harry A. George Harry A. George	Director	March 25, 2021
/s/ Michelle R. Griffin Michelle R. Griffin	Director	March 25, 2021
/s/ Donnie M. Hardison Donnie M. Hardison	Director	March 25, 2021
/s/ James T. LaFrance James T. LaFrance	Director	March 25, 2021
/s/ Lee R. McCracken Lee R. McCracken	Director	March 25, 2021



HTG INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE LOGO HTG Molecular Diagnostics, Inc. COMMON STOCK CUSIP 40434H 20 3 SEE REVERSE FOR CERTAIN DEFINITIONS THIS CERTIFIES THAT specimen is the owner of FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK, PAR VALUE $0.001 PER SHARE, OF HTG Molecular Diagnostics, Inc. transferable on the books of the Corporation by the holder hereof in person or by duly authorized Attorney, upon surrender of this Certificate, properly endorsed. This Certificate is not valid until countersigned and registered by the Transfer Agent and Registrar. WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers. Dated PRESIDENT SEAL SECRETARY AUTHORIZED SIGNATURE AND REGISTRAR TRANSFER AGENT Brooklyn, NY AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC COUNTERSIGNED AND REGISTERED

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM – as tenants in common
TEN ENT – as tenants by the entireties
JT TEN – as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT– _____ (Cust) Custodian _____ (Minor)
under Uniform Gifts to Minors Act _____ (State)

Additional abbreviations may also be used though not in the above list.

FOR VALUE RECEIVED, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.

Signature(s) Guaranteed:

_____

THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations: TEN COM as tenants in common TEN ENT as tenants by the entireties JT TEN as joint tenants with right of survivorship and not as tenants in common UNIF GIFT MIN ACT Custodian (Cust) (Minor) under Uniform Gifts to Minors Act (State) Additional abbreviations may also be used though not in the above list. FOR VALUE RECEIVED hereby sell, assign and transfer unto PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE (PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE) Shares of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint Attorney to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises. Dated NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER Signature(s) Guaranteed: THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.

Exhibit 4.13

DESCRIPTION OF COMMON STOCK

The following summary describes the material terms of the common stock, par value $0.001 per share, of HTG Molecular Diagnostics, Inc. ("we," "us" and "our"). The description of common stock is qualified by reference to our amended and restated certificate of incorporation and our amended and restated bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part.

General

Our amended and restated certificate of incorporation authorizes us to issue up to 26,666,667 shares of common stock In addition, under our amended and restated certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 10,000,000 shares of preferred stock, par value $0.001 per share, in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance could also have the effect of decreasing the market price of the common stock. The issuance of preferred stock also could have the effect of delaying, deterring or prevent a change in control of us.

Our board of directors has designated 51,270 shares of preferred stock as Series A Convertible Preferred Stock ("Series A Preferred"), 23,770 shares which are issued and outstanding as of the date of the Annual Report on Form 10-K of which this exhibit is a part. Each share of Series A Preferred is convertible into 6.67 shares of our common stock at the election of the holder, subject to proportional adjustment and beneficial ownership limitations as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.

Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. Holders of Series A Preferred are entitled to receive dividends on shares of Series A Preferred equal (on an as-converted to common stock basis) to and in the same form as dividends actually paid on our common stock.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock and holders of Series A Preferred will be entitled to share ratably (on an as-converted to common stock basis) in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely

affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change of control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that directors may only be removed, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (3) any action asserting a claim against the us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (4) any action asserting a claim against us governed by the internal affairs doctrine; and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then outstanding common stock.

Nasdaq Capital Market Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "HTGM."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

HTG MOLECULAR DIAGNOSTICS, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") of HTG Molecular Diagnostics, Inc. (the "***Company***") who is not also serving as an employee of the Company or any of its subsidiaries and who is designated by the Board or the Compensation Committee of the Board as eligible to receive compensation for his or her services as a member of the Board (each such member, an "***Eligible Director***") will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may waive all or part of the compensation that may otherwise be due to him/her by written notice to the Chief Executive Officer of the Company.

This policy may be amended at any time in the sole discretion of the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer and fee set forth below will be pro-rated based on the number of days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash retainers and committee service fees are vested upon payment.

1. Annual Board Service Retainer:

   a. All Eligible Directors: $**35,000** per year.

   b. Chairman of the Board: $**30,000** per year in addition, as applicable, to his/her compensation as an Eligible Director.

2. Annual Committee Member Service Retainer:

   a. Member of the Audit Committee: $**7,500** per year in addition to his/her compensation as an Eligible Director.

   b. Member of the Compensation Committee: $**6,000** per year in addition to his/her compensation as an Eligible Director.

   c. Member of the Nominating and Corporate Governance Committee: $**5,000** per year in addition to his/her compensation as an Eligible Director.

3. Annual Committee Chair Service Retainer:

   a. Chairman of the Audit Committee: $**15,000** per year in addition to his/her compensation as an Eligible Director.

   b. Chairman of the Compensation Committee: $**12,000** per year in addition to his/her compensation as an Eligible Director.

   c. Chairman of the Nominating and Corporate Governance Committee: $**10,000** per year in addition to his/her compensation as an Eligible Director.

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2020 Equity Incentive Plan, as it may be amended from time to time (the "***2020 Plan***"). All stock options granted pursuant to this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the 2020 Plan) of the underlying Common Stock of the Company (the "***Common Stock***") on the date of grant, and will have a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the 2020 Plan). All equity awards granted pursuant to this policy will vest in full upon a Change in Control (as defined in the 2020 Plan).

1. Initial Grant: On the date of each Eligible Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), each Eligible Director automatically will be granted, without further action by the Board or Compensation Committee of the Board, a stock option for **120,000** shares of Common Stock under the 2020 Plan. 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 such that the stock option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the 2020 Plan) through each such vesting date. An Eligible Director who, in the one year prior to his or her initial election to serve on the Board as a non-employee director, served as an employee of the Company or one of its subsidiaries will not be eligible for an initial grant.

2. Annual Grant: On the date of each annual Company stockholder meeting, each Eligible Director automatically will be granted, without further action by the Board or Compensation Committee of the Board, a stock option for **60,000** shares of Common Stock under the 2020 Plan. The shares will vest upon the earliest to occur of (i) the date that is 12 months following the date grant and (ii) the following year's annual Company stockholder meeting. In order to be deemed an Eligible Director for purposes of the annual grant, each Board member must have served as a member of the Board for a minimum of six months.

HTG MOLECULAR DIAGNOSTICS, INC.
SEVERANCE AND CHANGE IN CONTROL PLAN

APPROVED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS ON
OCTOBER 12, 2020

Section 1. INTRODUCTION.

The HTG Molecular Diagnostics, Inc. Severance and Change in Control Plan (the "***Plan***") is hereby established by the Compensation Committee of the Board of Directors of HTG Molecular Diagnostics, Inc. (the "***Company***") effective upon the date of approval set forth above. The purpose of the Plan is to provide for the payment of severance and/or Change in Control (as defined below) benefits to eligible employees of the Company. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

(a) "***Affiliate***" means any corporation (other than the Company) in an "unbroken chain of corporations" beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(b) "***Base Salary***" means base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect prior to any reduction that would give rise to an employee's right to a resignation for Good Reason (if applicable).

(c) "***Cause***" means, with respect to a particular employee, the meaning ascribed to such term in any written employment agreement, offer letter or similar agreement between such employee and the Company defining such term, and, in the absence of such agreement, means with respect to such employee, the occurrence of any of the following events, conditions or actions: (1) the employee's conviction of any felony or conviction of any crime involving fraud or dishonesty; (2) the employee's participation (whether by affirmative act or omission) in any material fraud, material act of dishonesty or other material act of misconduct against the Company; (3) the employee's willful and habitual neglect of such employee's duties, provided the employee has been given written notice of such neglect and, if curable, a reasonable opportunity to cure, not to exceed 30 days; (4) the employee's material violation of any fiduciary duty or duty of loyalty owed to the Company; (5) the employee's breach of any material term of any material contract between such employee and the Company which has a material adverse effect on the Company; (6) the employee's knowing violation of any material Company policy which has a material adverse effect on the Company; or (7) the employee's knowing violation of state or federal law in connection with the performance of such employee's job which has a material adverse effect on the Company. The determination whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion.

(d) "***Change in Control***" has the meaning ascribed to such term in the Equity Plan.

(e) "***Change in Control Period***" means the period commencing three months prior to the Closing of a Change in Control and ending 12 months following the Closing of a Change in Control.

(f) "***Closing***" means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

(g) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(h) "***Committee***" means the Board of Directors of the Company or the Compensation Committee of such Board.

(i) "***Company***" means HTG Molecular Diagnostics, Inc. or, following a Change in Control, the surviving entity resulting from such event.

(j) "***Confidentiality Agreement***" means the employee's Employee Confidential Information and Invention Assignment Agreement, as may be amended from time to time or any similar or successor document.

(k) "***Covered Termination***" means, with respect to an employee, a termination of employment that is due to (1) a termination by the Company without Cause (and other than as a result of the employee's death or Disability) or (2) the employee's resignation for Good Reason, and in either case of (1) or (2), results in such employee's Separation from Service.

(l) "***Disability***" means any physical or mental condition which renders an employee incapable of performing the work for which he or she was employed by the Company or similar work offered by the Company. The Disability of an employee shall be established if (i) the employee satisfies the requirements for benefits under the Company's long-term disability plan or (ii) if no long-term disability plan, the employee satisfies the requirements for Social Security disability benefits.

(m) "***Eligible Employee***" means an employee of the Company that meets the requirements to be eligible to receive Plan benefits as set forth in Section 2.

(n) "***Equity Plan***" means the HTG Molecular Diagnostics, Inc. 2020 Equity Incentive Plan, as amended from time to time, or any successor plan thereto.

(o) "***Good Reason***" for an employee's resignation means the occurrence of any of the following are undertaken by the Company without the employee's prior written consent:

(1) a material reduction in a such employee's base salary, which the employee and Company agree is a reduction of at least 10% of the employee's base salary (unless pursuant to a salary reduction program applicable generally to similarly situated employees of the Company);

(2) a material reduction in such employee's authority, duties or responsibilities;

(3) a material reduction in the authority, duties, or responsibilities of the supervisor to whom such employee is required to report;

(4) a material breach by the Company of any provision of this Plan or any other material agreement between such employee and the Company concerning the terms and conditions of such employee's employment with the Company; or

(5) a relocation of such employee's principal place of employment with the Company (or successor to the Company, if applicable) to a place that increases such employee's one-way commute by more than 50 miles as compared to such employee's then-current principal place of employment immediately prior to such relocation (excluding regular travel in the ordinary course of business); provided that if such employee's principal place of employment is his or her personal residence, this clause (4) shall not apply.

Notwithstanding the foregoing, in order for the employee's resignation to be deemed to have been for Good Reason, the employee must (a) provide written notice to the Company of such employee's intent to resign for Good Reason within 30 days after the first occurrence of the event giving rise to Good Reason, which notice shall describe the event(s) the employee believes give rise to Good Reason; (b) allow the Company at least 60 days from receipt of the written notice to cure the event (such period, the "***Cure Period***"), and (c) if the event is not reasonably cured within the Cure Period, the employee's resignation from all positions held with the Company is effective not later than 30 days after the expiration of the Cure Period.

(p) "***Participation Agreement***" means an agreement between an employee and the Company in substantially the form of **Appendix A** attached hereto, and which may include such other terms as the Committee deems necessary or advisable in the administration of the Plan.

(q) "***Plan Administrator***" means the Committee prior to the Closing and the Representative upon and following the Closing, as applicable.

(r) "***Representative***" means one or more members of the Committee or other persons or entities designated by the Committee prior to or in connection with a Change in Control that will have authority to administer and interpret the Plan upon and following the Closing as provided in Section 8(a).

(s) "***Section 409A***" means Section 409A of the Code and the treasury regulations and other guidance thereunder and any state law of similar effect.

(t) "***Separation from Service***" means a "separation from service" within the meaning of Treasury Regulations Section 1.409A-1(h), without regard to any alternative definition thereunder.

Section 2. ELIGIBILITY FOR BENEFITS.

(a) Eligible Employee. An employee of the Company is eligible to participate in the Plan if (i) the Plan Administrator has designated such employee as eligible to participate in the Plan by providing such employee a Participation Agreement; (ii) such employee has signed and returned such Participation Agreement to the Company within the time period required therein; and (iii) such employee meets the other Plan eligibility requirements set forth in this Section 2 and in the Participation Agreement. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons.

(b) Release Requirement. Except as otherwise provided in an individual Participation Agreement, in order to be eligible to receive benefits under the Plan, the employee also must execute a general waiver and release, in such a form as provided by the Company (provided that, for the avoidance of doubt, such release will include a commitment from the employee to comply with such employee's continuing obligations under such employee's Confidentiality Agreement, but will not include a release of any rights or claims for indemnification the employee may have pursuant to any written indemnification agreement with the Company to which the employee is a party, the Company's bylaws, or applicable law) (the "***Release***"), within the applicable time period set forth therein, and such Release must become effective in accordance with its terms, which must occur in no event more than 60 days following the date of the applicable Covered Termination.

(c) Plan Benefits Provided In Lieu of Any Previous Benefits. Except as otherwise provided in an individual Participation Agreement, this Plan shall supersede any change in control or severance benefit plan, policy or practice previously maintained by the Company with respect to an Eligible Employee and any change in control or severance benefits in any individually negotiated employment contract or other agreement between the Company and an Eligible Employee, including the terms of any equity award grant notices and agreements governing the Eligible Employee's outstanding equity awards that may apply upon a Change in Control and/or termination of such employee's service. Notwithstanding the foregoing, the Eligible Employee's equity awards shall remain subject to the terms and conditions of the applicable equity plan under which such awards were granted and no provision of this Plan shall be construed as to limit the actions that may be taken, or to violate the terms of such equity plan.

(d) Exceptions to Severance Benefit Entitlement. An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

(1) The employee is terminated by the Company for any reason (including due to the employee's death or Disability) or voluntarily terminates employment with the Company in any manner, and in either case, such termination does not constitute a Covered Termination. Voluntary terminations include, but are not limited to, resignation, retirement or failure to return from a leave of absence on the scheduled date.

(2) The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate.

(3) The employee is offered an identical or substantially equivalent or comparable position with the Company or an Affiliate. For purposes of the foregoing, a "substantially equivalent or comparable position" is one that provides the employee substantially the same level of responsibility and compensation and would not give rise to the employee's right to a resignation for Good Reason.

(4) The employee is offered immediate reemployment by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control and the terms of such reemployment would not give rise to the employee's right to a resignation for Good Reason. For purposes of the foregoing, "immediate reemployment" means that the employee's employment with the successor to the Company or an Affiliate or the purchaser of its assets, as the case may be, results in uninterrupted employment such that the employee does not incur a lapse in pay or benefits as a result of the change in ownership of the Company or the sale of its assets. For the avoidance of doubt, an employee who becomes immediately reemployed as described in this Section 2(d)(4) by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control shall continue to be an Eligible Employee following the date of such reemployment.

(5) The employee is rehired by the Company or an Affiliate and recommences employment prior to the date severance benefits under the Plan are scheduled to commence.

(e) Termination of Severance Benefits. An Eligible Employee's right to receive severance benefits under this Plan shall terminate immediately if, at any time prior to or during the period for which the Eligible Employee is receiving severance benefits under the Plan, the Eligible Employee:

(1) willfully breaches any material statutory, common law, or contractual obligation to the Company or an Affiliate (including, without limitation, the contractual obligations set forth in the Confidentiality Agreement and any other confidentiality, non-disclosure and developments agreement, non-competition, non-solicitation, or similar type agreement between the Eligible Employee and the Company, as applicable);

(2) fails to enter into the terms of the Confidentiality Agreement; or

(3) without the prior written approval of the Plan Administrator, engages in a Prohibited Action (as defined below). In addition, if benefits under the Plan have already been paid to Eligible Employee and the Eligible Employee subsequently engages in a Prohibited Action during the Prohibited Period (or it is determined that an Eligible Employee engaged in a Prohibited Action prior to receipt of such benefits), any benefits previously paid to the Eligible Employee shall be subject to recoupment by the Company on such terms and conditions as shall be determined by the Plan Administrator, in its sole discretion. The

"***Prohibited Period***" shall commence on the date of the Eligible Employee's Covered Termination and continue for the number of months corresponding to the Severance Period set forth in such Eligible Employee's Participation Agreement. A "***Prohibited Action***" shall occur if the Eligible Employee: (i) breaches a material provision of the Confidentiality Agreement and/or any obligations of confidentiality, non-solicitation, non-disparagement, no conflicts or non-competition set forth in the Eligible Employee's employment agreement, offer letter, any other written agreement between the Eligible Employee and the Company, or under applicable law; (ii) encourages or solicits any of the Company's then current employees to leave the Company's employ for any reason or interferes in any other manner with employment relationships at the time existing between the Company and its then current employees; or (iii) induces any of the Company's then current clients, customers, suppliers, vendors, distributors, licensors, licensees, or other third parties to terminate their existing business relationship with the Company or interferes in any other manner with any existing business relationship between the Company and any then current client, customer, supplier, vendor, distributor, licensor, licensee, or other third parties.

Section 3. AMOUNT OF BENEFITS.

(a) Benefits in Participation Agreement. Benefits under the Plan shall be provided to an Eligible Employee as set forth in the Participation Agreement.

(b) Additional Benefits. Notwithstanding the foregoing, the Committee may, in its sole discretion, provide benefits to individuals who are not Eligible Employees ("***Non-Eligible Employees***") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other individual, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

(c) Certain Reductions. In addition to Section 2(e) above, the Company, in its sole discretion, shall have the authority to reduce an Eligible Employee's severance benefits, in whole or in part, by any other severance benefits, pay and benefits provided during a period following written notice of a business closing or mass layoff, pay and benefits in lieu of such notice, or other similar benefits payable to the Eligible Employee by the Company or an Affiliate that become payable in connection with the Eligible Employee's termination of employment pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other similar state law or (ii) any Company policy or practice providing for the Eligible Employee to remain on the payroll for a limited period of time after being given notice of the termination of the Eligible Employee's employment, and the Plan Administrator shall so construe and implement the terms of the Plan. Any such reductions that the Company determines to make pursuant to this Section 3(c) shall be made such that any severance benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice (*i.e.*, any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Eligible Employee and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other

Eligible Employee. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

(d) Parachute Payments. Except as otherwise provided in an individual Participation Agreement, if any payment or benefit an Eligible Employee would receive from the Company or otherwise in connection with a Change in Control or other similar transaction (a "***280G Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such 280G Payment (a "***Payment***") shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for the Eligible Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Eligible Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

Unless the Eligible Employee and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change of control transaction triggering the Payment shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change of control transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to the Eligible Employee and the Company within fifteen (15) calendar days after the date on which the Eligible Employee's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by such

Eligible Employee or the Company) or such other time as requested by such Eligible Employee or the Company.

If the Eligible Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section 3(d) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Eligible Employee shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section 3(d) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section 3(d), the Eligible Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Section 4. RETURN OF COMPANY PROPERTY.

An Eligible Employee will not be entitled to any severance benefit under the Plan unless and until the Eligible Employee returns all Company Property. For this purpose, "***Company Property***" means all paper and electronic Company documents (and all copies thereof) and other Company property which the Eligible Employee had in his or her possession or control at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part). As a condition to receiving benefits under the Plan, an Eligible Employee must not make or retain copies, reproductions or summaries of any such Company documents, materials or property. However, an Eligible Employee is not required to return his or her personal copies of documents evidencing the Eligible Employee's hire, termination, compensation, benefits and stock options and any other documentation received as a stockholder of the Company.

Section 5. TIME OF PAYMENT AND FORM OF BENEFITS.

The Company reserves the right in the Participation Agreement to specify whether payments under the Plan will be paid in a single sum, in installments, or in any other form and to determine the timing of such payments. All such payments under the Plan will be subject to applicable withholding for federal, state, foreign, provincial and local taxes. All benefits provided under the Plan are intended to satisfy the requirements for an exemption from application of Section 409A to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly; *provided, however*, that to the extent such an exemption is not available, the benefits provided under the Plan are intended to comply with the requirements of Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly.

It is intended that (i) each installment of any benefits payable under the Plan to an Eligible Employee be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), (ii) all payments of any such benefits under the Plan satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9)(iii), and (iii) any such benefits consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemption from the application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(9)(v). However, if the Company determines that any severance benefits payable under the Plan constitute "deferred compensation" under Section 409A and the Eligible Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i), then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (A) the timing of such severance benefit payments shall be delayed until the earlier of (1) the date that is six months and one day after the Eligible Employee's Separation from Service and (2) the date of the Eligible Employee's death (such applicable date, the "***Delayed Initial Payment Date***"), and (B) the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the severance benefit payments that the Eligible Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of the severance benefits in accordance with the applicable payment schedule.

In no event shall payment of any severance benefits under the Plan be made prior to an Eligible Employee's Separation from Service or prior to the effective date of the Release. If the Company determines that any severance payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Eligible Employee's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Eligible Employee's Separation from Service occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective, solely for purposes of the timing of payment of severance benefits under this Plan, any earlier than the latest permitted effective date (the "***Release Deadline***"). If the Company determines that any severance payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, then except to the extent that severance payments may be delayed until the Delayed Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll date following the effective date of an Eligible Employee's Release, the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the severance benefit payments that the Eligible Employee would otherwise have received through such payroll date but for the delay in payment related to the effectiveness of the Release and (2) commence paying the balance, if any, of the severance benefits in accordance with the applicable payment schedule.

Section 6. TRANSFER AND ASSIGNMENT.

The rights and obligations of an Eligible Employee under this Plan may not be transferred or assigned without the prior written consent of the Company. This Plan shall be binding upon any entity or person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company without regard to whether or not such entity or

person actively assumes the obligations hereunder and without regard to whether or not a Change in Control occurs.

Section 7. Mitigation.

Except as otherwise specifically provided in the Plan, an Eligible Employee will not be required to mitigate damages or the amount of any payment provided under the Plan by seeking other employment or otherwise, nor will the amount of any payment provided for under the Plan be reduced by any compensation earned by an Eligible Employee as a result of employment by another employer or any retirement benefits received by such Eligible Employee after the date of the Eligible Employee's termination of employment with the Company.

Section 8. Clawback; Recovery.

All payments and severance benefits provided under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Plan Administrator may impose such other clawback, recovery or recoupment provisions as the Plan Administrator determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of common stock of the Company or other cash or property upon the occurrence of a termination of employment for Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for Good Reason, constructive termination, or any similar term under any plan of or agreement with the Company.

Section 9. Right to Interpret and Administer Plan; Amendment and Termination.

(a) Interpretation and Administration. Prior to the Closing, the Committee shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Committee shall be binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in this Plan to the "Committee" or "Plan Administrator" with respect to periods following the Closing shall mean the Representative.

(b) Amendment. The Plan Administrator reserves the right to amend this Plan at any time; *provided, however,* that any amendment of the Plan will not be effective as to a particular employee who is or may be adversely impacted by such amendment and has an effective Participation Agreement without the written consent of such employee.

(c) Termination. Unless otherwise extended by the Committee, the Plan will automatically terminate following satisfaction of all the Company's obligations under the Plan.

Section 10. No Implied Employment Contract.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved. This Plan does not modify the at-will employment status of any Eligible Employee.

Section 11. Legal Construction.

This Plan is intended to be governed by and shall be construed in accordance with the Employee Retirement Income Security Act of 1974 ("***ERISA***") and, to the extent not preempted by ERISA, the laws of the State of Arizona.

Section 12. Claims, Inquiries and Appeals.

(a) Applications for Benefits and Inquiries. Any application for benefits, inquiries about the Plan or inquiries about present or future rights under the Plan must be submitted to the Plan Administrator in writing by an applicant (or his or her authorized representative). The Plan Administrator is:

HTG Molecular Diagnostics, Inc.
Compensation Committee of the Board of Directors or Representative
Attention to: Corporate Secretary
3430 E. Global Loop
Tucson, Arizona 85706

(b) Denial of Claims. In the event that any application for benefits is denied in whole or in part, the Plan Administrator must provide the applicant with written or electronic notice of the denial of the application, and of the applicant's right to review the denial. Any electronic notice will comply with the regulations of the U.S. Department of Labor. The notice of denial will be set forth in a manner designed to be understood by the applicant and will include the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a description of any additional information or material that the Plan Administrator needs to complete the review and an explanation of why such information or material is necessary; and

(4) an explanation of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the applicant's right to bring a civil action

under Section 502(a) of ERISA following a denial on review of the claim, as described in Section 10(d) below.

This notice of denial will be given to the applicant within 90 days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional 90 days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial 90 day period.

This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the application.

(c) Request for a Review. Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within 60 days after the application is denied. A request for a review shall be in writing and shall be addressed to:

HTG Molecular Diagnostics, Inc.
Compensation Committee of the Board of Directors or Representative
Attention to: Corporate Secretary
3430 E. Global Loop
Tucson, Arizona 85706

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The applicant (or his or her representative) shall have the opportunity to submit (or the Plan Administrator may require the applicant to submit) written comments, documents, records, and other information relating to his or her claim. The applicant (or his or her representative) shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim. The review shall take into account all comments, documents, records and other information submitted by the applicant (or his or her representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(d) Decision on Review. The Plan Administrator will act on each request for review within 60 days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional 60 days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial 60 day period. This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the review. The Plan Administrator will give prompt, written or electronic notice of its decision to the applicant. Any electronic notice will comply with the regulations of the U.S. Department of Labor. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will set forth, in a manner calculated to be understood by the applicant, the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a statement that the applicant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim; and

(4) a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA.

(e) Rules and Procedures. The Plan Administrator will establish rules and procedures, consistent with the Plan and with ERISA, as necessary and appropriate in carrying out its responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial of benefits to do so at the applicant's own expense.

(f) Exhaustion of Remedies. No legal action for benefits under the Plan may be brought until the applicant (i) has submitted a written application for benefits in accordance with the procedures described by Section 10(a) above, (ii) has been notified by the Plan Administrator that the application is denied, (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 10(c) above, and (iv) has been notified that the Plan Administrator has denied the appeal. Notwithstanding the foregoing, if the Plan Administrator does not respond to an Eligible Employee's claim or appeal within the relevant time limits specified in this Section 10, the Eligible Employee may bring legal action for benefits under the Plan pursuant to Section 502(a) of ERISA.

Section 13. Basis of Payments to and from Plan.

The Plan shall be unfunded, and all cash payments under the Plan shall be paid only from the general assets of the Company.

Section 14. Other Plan Information.

(a) Employer and Plan Identification Numbers. The Employer Identification Number assigned to the Company (which is the "Plan Sponsor" as that term is used in ERISA) by the Internal Revenue Service is 86-0912294. The Plan Number assigned to the Plan by the Plan Sponsor pursuant to the instructions of the Internal Revenue Service is 510.

(b) Ending Date for Plan's Fiscal Year. The date of the end of the fiscal year for the purpose of maintaining the Plan's records is December 31.

(c) Agent for the Service of Legal Process. The agent for the service of legal process with respect to the Plan is:

HTG Molecular Diagnostics, Inc.

Attention to: Corporate Secretary
3430 E. Global Loop
Tucson, Arizona 85706

In addition, service of legal process may be made upon the Plan Administrator.

(d) Plan Sponsor. The "Plan Sponsor" is:

HTG Molecular Diagnostics, Inc.
3430 E. Global Loop
Tucson, Arizona 85706
(877) 289-2615

(e) Plan Administrator. The Plan Administrator is the Committee prior to the Closing and the Representative upon and following the Closing. The Plan Administrator's contact information is:

HTG Molecular Diagnostics, Inc.
Compensation Committee of the Board of Directors or Representative
3430 E. Global Loop
Tucson, Arizona 85706

The Plan Administrator is the named fiduciary charged with the responsibility for administering the Plan.

Section 15. STATEMENT OF ERISA RIGHTS.

Participants in this Plan (which is a welfare benefit plan sponsored by HTG Molecular Diagnostics, Inc.) are entitled to certain rights and protections under ERISA. If you are an Eligible Employee, you are considered a participant in the Plan and, under ERISA, you are entitled to:

(a) Receive Information About Your Plan and Benefits

(1) Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series), if applicable, filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration;

(2) Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500 Series), if applicable, and an updated (as necessary) Summary Plan Description. The Administrator may make a reasonable charge for the copies; and

(3) Receive a summary of the Plan's annual financial report, if applicable. The Plan Administrator is required by law to furnish each Eligible Employee with a copy of this summary annual report.

(b) Prudent Actions by Plan Fiduciaries. In addition to creating rights for Plan Eligible Employees, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Eligible Employees and beneficiaries. No one, including your employer, your union or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a Plan benefit or exercising your rights under ERISA.

(c) Enforce Your Rights. If your claim for a Plan benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan, if applicable, and do not receive them within 30 days, you may file suit in a Federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator.

If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or Federal court.

If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

(d) Assistance with Your Questions. If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

APPENDIX A

PARTICIPATION AGREEMENT

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Exhibit 10.18

SECOND AMENDMENT TO LEASE AGREEMENT
(Suite 300 - Laboratory)

This Second Amendment to Lease Agreement ("Amendment") is dated to be effective as of the 8th day of December, 2020 ("Effective Date"), by and between Pegasus Properties, L.P., a Wisconsin limited partnership ("Lessor"), and HTG Molecular Diagnostics, Inc., a Delaware corporation, formerly known as High Throughput Genomics, Inc. ("Lessee").

RECITALS

A. Lessor and Lessee entered that certain Standard Commercial-Industrial Multi Tenant Triple Net Lease, dated July 11, 2008 (the "Suite 300 Lease"), pursuant to which Lessor leases to Tenant approximately 12,600 square feet of office/warehouse/light manufacturing/R&D space ("Suite 300 Premises") in that certain building that is commonly known as 3430 E. Global Loop, Suite 300, Tucson, Arizona 86706, as more particularly described in the Suite 300 Lease.

B. On August 4th, 2015 Lessor and Lessee entered into the First Amendment to the Suite 300 Lease Agreement extending the Lease by approximately 5 years among other agreements.

C. For reference purposes only, Lessor and Lessee also entered into that certain Standard Commercial-Industrial Multi Tenant Triple Net Lease, dated May 11, 2011 (as it may be amended on or around the Effective Date, the "Suite 100 Lease"), pursuant to which Lessor leases to Lessee approximately 17,500 square feet of office and warehouse space ("Suite 100 Premises") in that certain building that is commonly known as 3430 E. Global Loop, Suite 100, Tucson, Arizona 86706, as more particularly described in the Suite 100 Lease. The parties acknowledge that the Suite 100 Lease constitutes a separate legal obligation from the Suite 300 Lease for all purposes except as expressly set forth herein.

D. Lessor and Lessee now desire to, among other things, extend the lease term, amend the option to renew the Suite 300 Lease.

E. All capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Suite 300 Lease.

Now therefore, in consideration of the covenants and obligations contained herein, Lessor and Lessee agree as follows:

AGREEMENTS

1. **Recitals.** The Recitals above are true and correct and form a part of this Amendment.

2. **Extension of Term**. The Term of the Suite 300 Lease is hereby extended for a period of one (1) year, commencing on February 1st 2021, and expiring at 11:59 PM, Arizona time, on January 31st , 2022 which will also be referred to as the Expiration Date referred to in the Suite 300 Lease, subject to further renewal options as set forth in Section 2 below.

3. **Renewal Options**. Section 3.2 of the Suite 300 Lease is replaced, and will read in its entirety, as follows: Lessee shall have one option to renew the Suite 300 Lease for an additional period of three (3) years upon the same terms and conditions of the Suite 300 Lease as amended herein ("Renewal Term"), except that the Lease Rate will be set at rates currently applicable for like/kind buildings within the market but in no event less than the last rent rate (incl. annual increases if any) paid by Lessee. If Lessee elects to exercise such option to renew, Lessee shall give Lessor written notice of exercise of the option not later than October 31st 2021.

4. **Base Rent**.

(a) Notwithstanding anything in the Suite 300 Lease to the contrary, commencing on February 1st, 2021 and continuing to January 31st, 2022 the monthly base rent for the Suite 300 Premises shall be Fifteen Thousand Seven Hundred Thirty Five and no/100 dollars ($15,735), payable in accordance with the terms and conditions of the Suite 300 Lease, as amended in the First Amendment and pursuant to this Amendment.

5. **No Other Changes.** Except as modified herein and in the First Lease Amendment, all terms and conditions of the Suite 300 Lease shall remain unchanged and in full force and effect.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

IN WITNESS WHEREOF the parties have caused their respective duly authorized representatives to execute this Amendment as of the Effective Date.

LESSOR:	LESSEE:
Pegasus Properties, L.P.	HTG Molecular Diagnostics
By:/s/ Matt Schmidt Matt Schmidt Managing Partner	By:/s/ Shaun McMeans Shaun McMeans SVP and Chief Financial Officer

Exhibit 10.20

THIRD AMENDMENT TO LEASE AGREEMENT
SUITE 100 LEASE

This third Amendment to Lease Agreement ("Amendment") is dated to be effective as of the 8th of December, 2020 ("Effective Date"), by and between Pegasus Properties, L.P., a Wisconsin limited partnership ("Lessor"), and HTG Molecular Diagnostics, Inc., a Delaware corporation, formerly known as High Throughput Genomics, Inc. ("Lessee").

RECITALS

A. Lessor and Lessee entered that certain Standard Commercial-Industrial Multi Tenant Triple Net Lease, dated May 11, 2011 (and as amended by that First Amendment to Lease Agreement on August 4, 2015, the "Suite 100 Lease"), pursuant to which Lessor leases to Tenant approximately 17500 square feet of office/warehouse/light manufacturing/R&D space ("Suite 100 Premises") in that certain building that is commonly known as 3430 E. Global Loop, Suite 100, Tucson, Arizona 86706, as more particularly described in the Suite 100 Lease.

B. For reference purposes only, Lessor and Lessee also entered into that certain Standard Commercial-Industrial Multi Tenant Triple Net Lease, dated July 11th 2008 (and as amended by that First Amendment to Lease Agreement on August 4, 2015, specific to Suite 300, the "Suite 300 Lease"), pursuant to which Lessor leases to Lessee approximately 12,600 square feet of office/warehouse/light manufacturing/R&D space ("Suite 300 Premises") in that certain building that is commonly known as 3430 E. Global Loop, Suite 100, Tucson, Arizona 86706, as more particularly described in the Suite 300 Lease. The parties acknowledge that the Suite 300 Lease constitutes a separate legal obligation from the Suite 100 Lease for all purposes except as expressly set forth herein.

C. The Second Amendment as of January 28th 2019 to the Suite 100 Lease added approximately 7,000 square feet of office/warehouse/light manufacturing/R&D space (Suite 200), to the Suite 100 Lease and addressed certain improvements to be constructed by Lessee in the Suite 200 Premises.

D. Lessor and Lessee now desire to, among other things, extend the lease term, amend the option to renew the Suite 300 Lease.

E. All capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Suite 100 Lease.

Now therefore, in consideration of the covenants and obligations contained herein, Lessor and Lessee agree to amend the Suite 100 Lease as follows:

AGREEMENTS

1. **Recitals.** The Recitals above are true and correct and form a part of this Amendment.

2. **Extension of Term**. The Term of the Suite 100 Lease is extended until 11:59 PM, Arizona time, on January 31st, 2022, which will also be referred to as the Expiration Date referred to in the Suite 100 Lease, subject to the renewal options discussed below.

3. **Renewal Options**. Section 3.2 of the Suite 100 Lease is replaced, and will read in its entirety, as follows: Lessee shall have one option to renew the Suite 100 Lease for an additional period of three (3) years upon the same terms and conditions of the Suite 100 Lease as amended herein ("Renewal Term"), except that the Lease Rate will be set at rates currently applicable for like/kind buildings within the market but in no event less than the last rent rate (incl. annual increases if any) paid by Lessee. If Lessee elects to exercise such option to renew, Lessee shall give Lessor written notice of exercise of the option not later than October 31st 2021.

4. **Base Rent and Term for Suite 200**. Commencing on the February 1st 2021, and continuing through January 31st, 2022 unless otherwise extended pursuant to the terms of the Suite 100 Lease and this Amendment, Lessee will pay Lessor monthly base rent for the Suite 100/200 Premises equal to twenty one thousand two hundred forty two and no/100 dollars ($21,242.00), payable in accordance with the terms and conditions of the Suite 100 Lease.

5. **Lessee Improvements**. Under item 7 of the Second Amendment Lessee was entitled to a maximum of $100,000 of Suite 200 improvements amortized over 5 years at an interest rate of 5%. Due to shortened renewal term in the Third Lease Amendment the Lessor will limit the amount of Lessor's reimbursement for Lessee's planned improvements to a total amount of
$ 50,000. Additional $50,000 will be available if and when the Renewal Option under item 3 would be exercised by the Lessee. When Lessee initiates such improvements Lessee must notify Landlord of their nature and cost at least 30 days prior to starting a modification or alteration. The amount actually paid by Landlord for the Suite 200 Improvements will be paid to Landlord as additional Suite 100/200 Rent in equal monthly payments amortized over five years at an interest rate of 5 %, beginning on the first full month after the Suite 200 Improvements are completed. Should Lessee terminate the Suite 100 Lease at any time before the Expiration Date or choose to not renew the Suite 100 Lease within the timeframe permitted, the unpaid balance of Suite 200 Improvements not repaid to Landlord as additional rent (less interest) will be due to Lessor within 15 days of termination of the Suite 100 Lease.

6. **No Other Changes**. Except as modified herein and in the Second Lease Amendment, all terms and conditions of the Suite 100 Lease shall remain unchanged and in full force and effect.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

IN WITNESS WHEREOF the parties have caused their respective duly authorized representatives to execute this Amendment as of the Effective Date.

LESSOR:	LESSEE:
Pegasus Properties, L.P.	HTG Molecular Diagnostics
By:/s/ Matt Schmidt Matt Schmidt Managing Partner	By:/s/ Shaun McMeans Shaun McMeans SVP and Chief Financial Officer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

HTG Molecular Diagnostics, Inc.
Tucson, Arizona

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-229045 and 333-234173) and Form S-8 (Nos. 333-203930, 333-208325, 333-210401, 333-216942, 333-222571, 333-229303, 333-231349, 333-235961, 333-248207 and 333-252142) of HTG Molecular Diagnostics, Inc. of our report dated March 25, 2021, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Los Angeles, California
March 25, 2021

Exhibit 31.1

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

I, John L. Lubniewski, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2020 of HTG Molecular Diagnostics, Inc.

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

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

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

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

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

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

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

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

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

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

Date: March 25, 2021

By: /s/ John L. Lubniewski

John L. Lubniewski
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Shaun D. McMeans, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2020 of HTG Molecular Diagnostics, Inc.

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

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

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

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

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

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

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

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

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

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

Date: March 25, 2021

By: /s/ Shaun D. McMeans
Shaun D. McMeans
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of HTG Molecular Diagnostics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 25, 2021

By: /s/ John L. Lubniewski

John L. Lubniewski
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of HTG Molecular Diagnostics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 25, 2021

By: /s/ Shaun D. McMeans

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