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, 2021

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, 2021 (the last business day of the Registrant's most recently completed second fiscal quarter), was $42,885,725.

The number of shares of Registrant's Common Stock outstanding as of March 15, 2022 was 7,590,733.

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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;
- 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 principal 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 that 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.
- 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 at all. If available, financing terms may lead to significant dilution of our stockholders' equity.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share prices.
- If we are unable to successfully commercialize our products, our business may be adversely affected.
- COVID-19 has adversely affected our business and is expected to have an impact on our business for the foreseeable future.
- 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.
- 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 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 HTG Therapeutics business strategy may require significant investments in working capital and may not generate any revenue.
- 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 and enter into strategic development collaborations and licensing arrangements with third parties to develop diagnostic tests, as well as therapeutic development partnerships and collaborations.
- We are dependent on third-party suppliers for certain subcomponents of our products, including a single supplier for one subcomponent of our HTG EdgeSeq instruments.
- 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 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 future 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 life sciences company advancing precision medicine through our innovative transcriptome-wide profiling technology. Building on more than a decade of pioneering innovation and partnerships with biopharma leaders and major academic institutes, our proprietary next-generation HTG EdgeSeq technology is designed to make the development of life science tools and diagnostics more effective and efficient and to unlock a differentiated and disruptive approach to drug discovery.

Our product and service solutions enable 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 system, 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. 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 companion diagnostic ("CDx") tests.

Our existing 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. We believe that our target customers and collaborators desire high quality molecular profiling data in a multiplexed panel format from increasingly smaller and less invasive samples, providing our customers and collaborators with the option to analyze such data locally to minimize turnaround time and cost.

Biopharmaceutical companies are continually working to improve their drug development processes and the efficacy and safety of their drugs. We believe that our technology can support these initiatives by providing a seamless solution from biomarker discovery to a CDx 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 CDx 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.

In addition, we believe that our newly formed drug discovery business unit will allow us to leverage our proprietary HTG Transcriptome Panel ("HTP") and epitranscriptome profiling technologies and apply them early in the drug discovery process in conjunction with our machine learning-based chemical library design platform, to ultimately yield de-risked drug candidate molecules with greater potential for clinical success.

2021 Highlights and Recent Developments

Our development efforts over the past 18 months have been primarily focused on completing feasibility and development of our HTG Transcriptome Panel, including supporting our Early Adopter Program ("EAP"), where approximately 30 scientific collaborators throughout the U.S. and EU have partnered with us to explore potential applications of HTP in their research and clinical programs. We expect our EAP collaborators to assist us with customer testimonials, white papers, technical notes and peer-reviewed publications highlighting their use of HTP and overall experience relative to alternative technologies. The release of HTP, coupled with our existing whole transcriptome miRNA panel, is expected to allow us to not only continue to expand our position within oncology, but to diversify the use of our panels in other critical markets such as immunology, infectious disease, diabetes, cardiology and neurology. We also expect to focus our future development efforts on the expansion of the sample types available for use with both of these assays, with an initial focus on liquid biopsies.

In the future, we expect to grow our active installed base and drive larger consumable annuities as customer demand for our menu of proprietary panels, including HTP, increases as we 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 laboratory developed tests ("LDT") under Clinical Laboratory Improvement Amendments ("CLIA") regulations. We remain focused on high quality instrument placements and consumable pull through as the primary indicators of future commercial adoption and success in our business.

We also announced the formation of our new drug discovery business unit, HTG Therapeutics, in June 2021 with the addition of several highly experienced drug development professionals to our leadership team. HTG Therapeutics intends to utilize our HTP and epitranscriptome profiling technologies, integrated with a machine learning-based chemical library design platform to better-inform the design and selection of drug candidate molecules. Working with our Tucson-based research and development teams, HTG Therapeutics has engaged several external collaborators who are expected to contribute meaningful sample cohorts across multiple disease and therapy areas to identify early candidate molecules with therapeutic promise. These efforts are aimed at the generation of high-quality primary data that we believe could lead to new pharma partnerships in drug discovery and early development by the second half of 2022 and beyond.

COVID-19 and international efforts to control its spread have significantly curtailed the movement of people, goods and services worldwide, including in regions where we sell our products and services and conduct our business over the past year. We experienced a significant slowing in our product and product-related services revenue beginning in March 2020 and throughout the year ended December 31, 2021 due to continued disruptions to our customers' businesses from the pandemic and, in many instances, their prioritization of projects in areas related to COVID-19. In addition, we have experienced extended shipment times and increases in cost of product as ongoing supply chain disruptions have impacted the ability of certain suppliers to produce the materials necessary to build our products and perform our testing services. Despite the impacts of COVID-19 on our revenue and operations, we met all of our key development milestones throughout 2020 and 2021 and have not experienced any substantive manufacturing delays from raw material shortages. While most of our customers have now reopened their facilities, at least on a limited basis, it remains unknown whether COVID-19 will continue to materially impact our financial condition, liquidity and results of operations in future periods due to further shutdowns, social distancing measures or illness.

Our Strategy

Our objective is to establish our solutions as the standard in molecular profiling, CDx development and molecular diagnostics, and to make their benefits accessible to all molecular labs from research to the clinic and from discovery to diagnostics. We believe our HTG EdgeSeq can be leverage into a number of revenue verticals. In our profiling business, we have historically focused on growing our research use only ("RUO") profiling, molecular diagnostics and companion diagnostic collaboration opportunities. In addition, we believe there is an opportunity to expand our HTG EdgeSeq technology platform into other areas, including drug discovery.

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 microRNA 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. In 2021, we further expanded our product offerings and capabilities with the release of our HTP Transcriptome Panel, allowing customers to measure approximately 20,000 mRNA targets from the human transcriptome. This product enables gene expression analysis of the transcriptome from significantly less sample input and from lower quality samples, as a result of its reliance on our HTG EdgeSeq proprietary technology. We further expect this product to accelerate the expansion of our target customer base outside of oncology and autoimmune and into markets such as diabetes, cardiology and neurology.
- *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 CLIA certified labs to develop molecular diagnostic tests or to enable LDT development. We further expect HTP 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, 2021, our technology and products were used in 62 active development programs across leading biopharmaceutical companies which are incorporating biomarkers and potentially companion diagnostics in their drug development programs. We are able to develop novel RNA-based gene classifiers to help biopharmaceutical companies and leading translational medicine researchers better understand and predict durable response to drug candidates. We may also develop novel RNA profiling tests that can provide important biomarker information in immuno-oncology, autoimmune and other disease areas such as diabetes, cardiology and neurology. In 2020, we signed a 10-year non-exclusive agreement with QIAGEN Manchester Limited ("QML") to leverage its global commercial expertise and global distribution reach specifically for CDx assays as new companion diagnostics collaboration opportunities are identified in the future.
- *Leverage our existing capabilities to expand the utility of our HTG EdgeSeq proprietary technology through HTG Therapeutics.* HTG Therapeutics is focused on improving the existing drug discovery process by using our proprietary HTG EdgeSeq technologies. We believe that the benefits of our proprietary technology, including the ability to cost-effectively generate high volumes of relevant data in a short period of time, make HTG Therapeutics well-suited to improve upon and potentially disrupt existing early-stage drug discovery methods. HTG Therapeutics intends to use our HTP and epitranscriptome profiling technologies, integrated with a machine learning-based chemical library design platform, to better-inform the design and selection of drug candidate molecules that will be intrinsically de-risked and therefore, have increased opportunities for development success.

  Through the development of our therapeutics business strategy and building of a leadership team to support the strategy in the second half of 2021, we believe we can now complete initial proof of approach in the first half of 2022 and continue on to focus on delivering therapeutic candidate molecules for novel and well validated targets in the second half of 2022 and beyond. Specifically, we are producing an initial whitepaper that will capture the foundational aspects of our novel approach to drug discovery in the first quarter of 2022 and expect to follow that with an additional proof-of-approach whitepaper in the second quarter of 2022. Through the second half of 2022, we expect to design multiple chemical libraries for our first therapeutic target of focus and to complete cell-based model screens for transcriptomic profiling. The data generated from this process is expected to inform chemistry for further optimization, with the goal of yielding well annotated and significantly de-risked drug candidates suitable for further development. We believe this model will be used to identify subsequent drug candidates that will either be licensed to drug development partners at this stage or potentially retained internally for progression into early development, in an effort to further increase the value of the assets prior to licensing or partnering.
- *Establish collaborations with biopharmaceutical companies potentially informed by HTG Therapeutics efforts in the future.* We believe collaborations with biopharmaceutical companies with late-stage drug development programs have the potential to create additional companion diagnostic consumables revenue. In addition, our plans to improve upon the existing drug discovery processes through HTG Therapeutics are expected to inform or drive future collaborative development programs with drug candidate molecules that are intrinsically de-risked and have a greater potential for success in development.
- *Continue to establish our systems workflow as the best solution for RNA clinical sequencing*. We intend to continue to establish our technology as the optimal complementary workflow with next-generation sequencers. We believe our differentiated HTG EdgeSeq chemistry will accelerate adoption of RNA biomarkers 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 profiling business through new applications and expansion into new disease states and sample types*. Over the past two years, 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.

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 gene 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 market for RNA-Seq 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 deaths of 17.0 million people per year 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 correct 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.

Drug Discovery for the Biopharmaceutical Sector

The biopharmaceutical sector has increasingly relied on the "open science" model whereby companies pursue a diverse set of strategies leveraging internal research and development efforts as well as turning to external research and development, scientific collaborations and in-licensing opportunities to advance new drug discoveries, meet currently unmet needs and help more patients. Fully integrated pharmaceutical companies have evolved to use open science as a ground to supplement their internal pipeline efforts with new drug candidates and/or new emerging technologies. It is not uncommon among the fully integrated companies to have strategic goals where half of the pipeline is from internal efforts whereas the remaining half is populated through assets that are either in-licensed, partnered or acquired through strategic acquisitions. Some fully integrated pharmaceutical companies rely solely on external science and innovation.

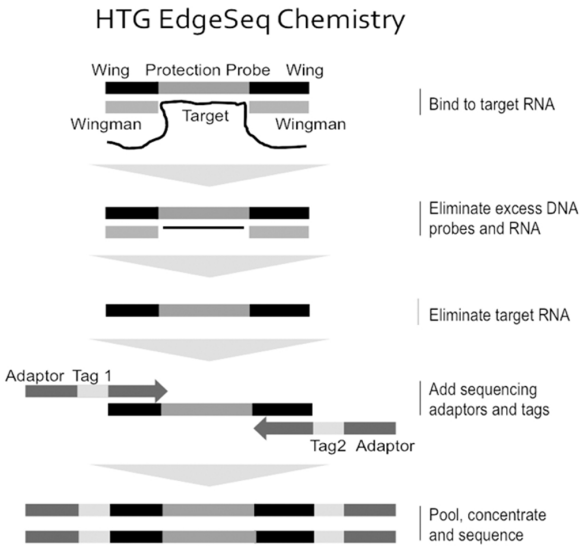
We believe that our approach of utilizing our established RNA profiling capabilities, integrated into a drug discovery platform with advanced medicinal chemistry technologies, will result in more well-informed molecule design and selection and potentially provide multiple revenue opportunities. These revenue opportunities may include collaboration or licensing arrangements for any small molecule drug candidates we generate, either at early- or mid-stage development, out-licensing our technology to pharmaceutical companies to enable them to implement our advanced drug discovery approach into their own internal discovery efforts, and potentially new companion diagnostic opportunities to support the related clinical development programs for those molecules.

Our Profiling 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.

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 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 to form a hybridized heteroduplex. This produces an approximately 1:1 ratio of DNA protection probes to the RNA targeted in the sample. DNA protection probes are labeled with sequencing adaptors and molecular barcodes in a PCR reaction. The labeled DNA protection probes are cleaned up, quantified, 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 gene targets.* Measuring multiple genes in a single reaction can be challenging with competitive technologies due to the complex interactions of reaction components. With our HTG EdgeSeq chemistry, we can profile almost 22,000 genes using a single panel. 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 the sample. These time-consuming steps may lead to some RNA loss and bias the test outcome. In formalin fixed paraffin embedded ("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 yield. These biases introduced by RNA extraction cannot be overcome and may be propagated 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-quantitative PCR ("RT-qPCR") and traditional RNA sequencing, require conversion of RNA into complementary DNA (cDNA) for analysis. When damaged and fragmented RNA is used, these small RNA strands become increasingly difficult to convert into cDNA in an accurate and reproducible manner. Our proprietary chemistry does not require conversion of the RNA to cDNA by reverse transcription, removing a technical difficulty experienced with competitive technologies.
- *Short protection probes.* Many samples contain RNA degraded by various combinations of storage conditions, 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 the introduction of biases, sample degradation and increased opportunities for operator 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, eliminate cross-contamination 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 hundreds or thousands of RNA targets in a single panel. The sample library is prepared on the processor, then labeled with molecular sequencing adaptors and tags. The labeled samples are cleaned up, quantified, 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 panels are currently 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, 2021, we had an installed base of 81 instruments (consisting of 59 systems sold, five covered under reagent rental or standard rental agreements, 10 evaluation units and seven systems with key opinion leaders).

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. 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 RNA modifications 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 FFPE tissue, cultured cells, and blood-based sample types such as PAXgene, 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-qPCR, our chemistry does not require cDNA synthesis. Compared to traditional RNA sequencing, our chemistry does not require extraction, cDNA synthesis, shearing, rRNA depletion, among other library preparation steps. We believe that the elimination of these steps helps prevent biases associated with these steps, sample degradation and opportunities for operator 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, 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 for researchers and can be used to deliver patient reports. The HTG EdgeSeq parser software, which processes the data generated from the NGS platform, is modular so that new panels can be added without any changes to the underlying software or hardware. We believe the simplicity of our bioinformatics solution will help drive the adoption of our platform.

Revenue and Commercialization of our Products

We currently market proprietary molecular profiling panels targeting early and late-stage drug development programs with potential breakthrough therapies. We market these panels to biopharmaceutical companies, with which we may 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 product and product-related services revenue is generated through the sale of our profiling instruments and consumables, sample processing services and custom assay design services to biopharmaceutical companies, academic research centers and molecular testing laboratories.

Customers can purchase our HTG EdgeSeq instrument and related consumables, which consist primarily of our proprietary molecular profiling panels and other assay components. Our currently marketed panels are:

- *HTG Transcriptome Panel*. HTP is expertly designed to provide extensive coverage of most human mRNA transcripts. The panel can simultaneously interrogate 19,398 gene targets using FFPE, PAXgene and extracted RNA samples, generating data for up to 96 samples in less than three days. HTP uses our proprietary workflow and leverages the sensitivity and dynamic range of NGS, allowing researchers to generate reliable results using limited sample amount.
- *HTG EdgeSeq miRNA Whole-Transcriptome Assay*. Human microRNAs ("miRNA") are short non-coding strands of RNA that are used by the cell for gene expression 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 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 (above), 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 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 EdgeSeq Pan B-Cell Lymphoma Panel*. The HTG EdgeSeq Pen B-Cell Lymphoma Panel measures gene expression of mRNA targets commonly associated with indolent and aggressive lymphomas to help identify lymphoma subgroups to elucidate the transcription response of disease state and drug therapy. With 298 gene targets, the HTG EdgeSeq Pan B-Cell Lymphoma Panel addresses the heterogeneity of B-cell lymphomas, including published signatures and drug targets.
- *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 Mouse mRNA Tumor Response Panel.* The HTG EdgeSeq Mouse mRNA Tumor Response Panel detects 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.
- *HTG EdgeSeq DLBCL Cell of Origin Assay EU and HTG EdgeSeq ALKPlus EU*. HTG EdgeSeq DLBCL Cell of Origin Assay EU and HTG EdgeSeq ALK*Plus* EU are IVD assays. These products have obtained CE-marking in Europe where they are available for diagnostic use by customers in Europe and are not available for sale in North America. With the EU's transition to IVD Medical Device Regulation scheduled for May 2022, we would need to comply with these requirements in order for these products to remain on the EU market other than for research use only. At this time, we do not intend to attempt compliance with these requirements and, where applicable, do not have appropriate licenses or permits to conduct diagnostic testing services.

Customers can also access our technology through contracted services. Pre-clinical services, including custom assay design and sample processing services provided by our VERI/O laboratory, 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.

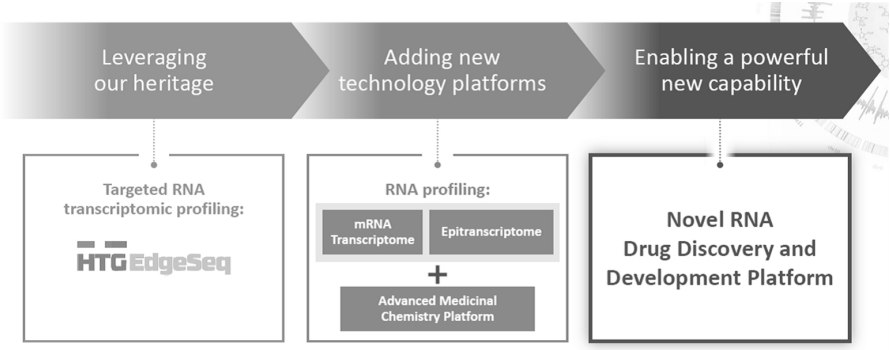
Through collaboration with biopharmaceutical company customers, we believe we are uniquely positioned to provide comprehensive services to design, develop and manufacture custom targeted assays with complex molecular diagnostic signatures as investigational use only ("IUO") assays for use in global prospective 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 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.

We have previously generated collaborative development services revenue through three statements of work entered into under our prior Master Assay Development, Commercialization and Manufacturing Agreement with QML. Under these agreements, we and QML combined our technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of CDx assays in support of and in conjunction with, biopharmaceutical companies' drug development programs. Remaining agreed upon procedures associated with these statements of work were completed in 2020 and no additional collaborative development services programs were entered into in 2021.

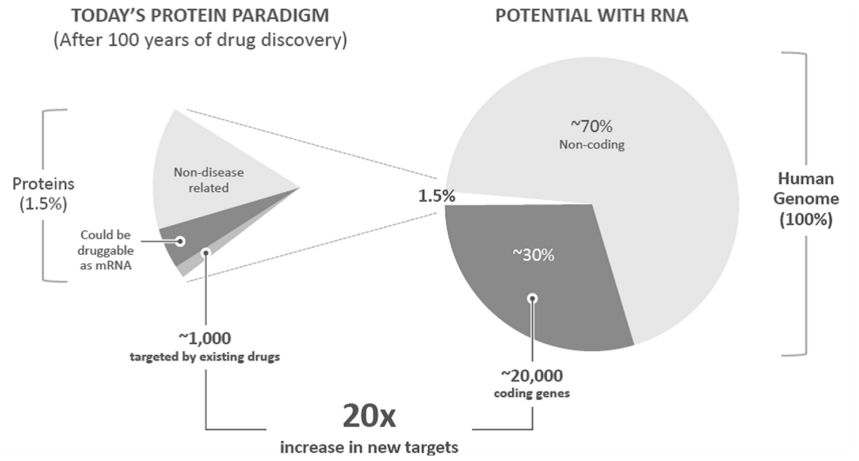
Our Drug Discovery Approach

Currently, approximately 90% of drugs fail in clinical development due to insufficient efficacy and/or safety issues and, in many instances, these issues are not revealed until considerable time has passed and tens or even hundreds of millions of dollars have been spent in the discovery and development stages of these programs. Through key learnings from our collaborative development services experiences, we have designed a new approach to drug discovery that leverages the benefits of our HTP and epitranscriptome profiling technologies in RNA profiling, sequencing and other scientific applications, including drug discovery and development. We believe the competitive advantages provided by our technology, compared with other profiling technologies, are the ability to process smaller sample volumes of multiple sample types with faster turnaround times and a simplified workflow.

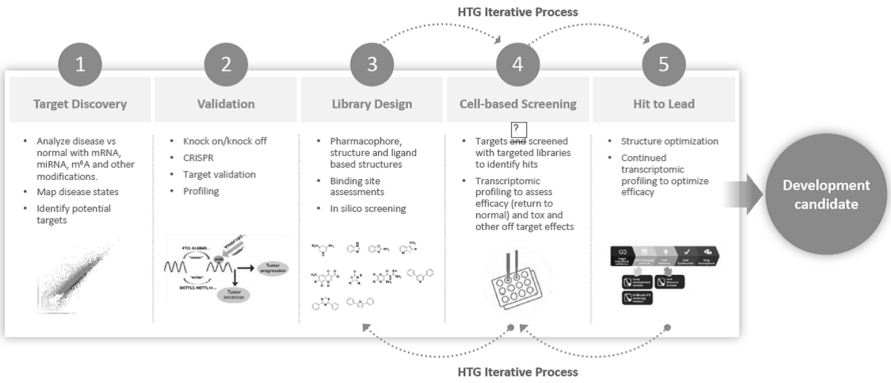
Throughout 2021, we strengthened our HTG EdgeSeq technology platform and added new profiling capabilities, including epitranscriptomic profiling, which currently provides the capability to generate over 40,000 biological data points from each experimental sample. By leveraging these profiling technologies in the drug discovery process, integrated with an advanced machine learning-based medicinal chemistry approach, we have established a novel transcriptome-informed small molecule discovery platform at the core of our HTG Therapeutics business unit which we believe will generate drug candidate molecules that are intrinsically de-risked and will have greater potential for clinical development success when compared to currently existing early-stage drug discovery methods in the biopharmaceutical industry. We have begun our initial studies using validated targets and cell-based test systems and believe this approach with extensive, new data generated from the application of these RNA-based profiling technologies will allow us to significantly de-risk drug candidate molecule selection earlier in the process, allowing for greater confidence in development candidate nomination earlier in the drug development process. This is expected to increase the probability of success in clinical development, reducing the likelihood of costly failed clinical trials and ultimately development failures. We believe this approach to small molecule discovery can be applied agnostically across therapeutic areas and is scalable and flexible, allowing us to adapt our strategic and therapeutic focus rapidly as new information emerges on the pathogenesis of diseases.



We believe that our approach will potentially provide multiple revenue opportunities, including collaboration or licensing arrangements for small molecule drug candidates we generate from as early as lead optimization through early preclinical development, the out-licensing of our technology to pharmaceutical companies to enable them to implement our advanced drug discovery approach into their own internal discovery efforts, and potentially new companion diagnostic opportunities to support the related clinical development programs for molecules that are brought forward through this novel discovery approach.



In the first half of 2022, we expect to focus our efforts on a series of milestones aimed at experimentally demonstrating our proof of approach of using our core and extended technology solutions early in the drug discovery process. We also expect to continue our efforts to identify early therapeutic drug candidate molecules that we would look to out-license or potentially partner with biotech or pharma companies to take into early development in the second half of 2022. As additional candidates are identified, we may seek to retain certain candidates internally to be advanced through early development, with the intention to increase the value of these pipeline assets before moving to license or partner for further development. Finally, we expect to maintain the rights and the opportunity to solely develop new CDx assays relating to these drug candidates as they move through the increasingly advanced stages of development with our collaboration partners, further growing our existing gene expression profiling business.



The market has been slow to adopt RNA technology due to the high cost and long timelines experienced by researchers and biopharmaceutical companies using other existing RNA technologies. We believe our core profiling technology and the logical application of it to drug discovery will allow us to offer broader and more practical solutions for a wide range of new, potential customers and collaboration partners in this space.

Research and Development

We are committed to the continued evolution of our HTG EdgeSeq technology platform, including development of new and continuous improvement of the performance and reliability of existing assays, as well as the expansion of its uses for drug discovery and other areas where we and our customers believe RNA can be used to advance scientific discovery. We have assembled an experienced research and development team with the scientific, engineering, software and process talent that we believe is necessary to successfully grow our business. In addition, we added resources to our leadership team throughout the second half of 2021 with the expertise to drive our HTG Therapeutics business unit and its strategic objectives in the area of drug discovery.

As of December 31, 2021, our research and development team consisted of 27 employees across the disciplines of research and development, platform development and chemistry, therapeutics and bioinformatics.

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, 2021, our U.S. sales and marketing organization consisted of 16 employees including 10 in direct sales or sales management, four in sales support and two in marketing. In addition to our U.S. sales team, as of December 31, 2021, we had six 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. Although there are a limited number of manufacturers for components of this type, we believe that other suppliers could provide similar products on comparable terms if identification of additional sources should be necessary in the future. 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. Similarly, 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 and could adversely affect sales and operating results.

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 (acquired by Labcorp), 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.

The biopharmaceutical sector is populated with companies advancing new or differentiated approaches to discovery and experimental therapeutics by way of different platform technologies or modalities with intent for application to specific disease areas through focus on pharmacologic targets or through phenotypic approaches. Each approach has inherent scientific risks that are intrinsic to the discovery sciences for molecule selection, as these efforts provide the early pipeline assets that progress into the more established and regulated stages of drug development. We believe that our approach, which is grounded in our exceptional RNA profiling capabilities now being applied to experimental systems used in conjunction with an advanced medicinal chemistry technology, will result in more well-informed design and selection of small molecule drug candidates very early on in the drug discovery process, thereby allowing for greater chances for success of these molecules. As such, we believe our approach differentiates us from the competition as the early de-risking of small molecule design and selection is at the core of our strategy, with the flexibility for application across multiple therapy areas.

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.

Since 2020 and throughout the year ended December 31, 2021, we incurred legal expenses to defend our core intellectual property against potential infringement by a competitor. These legal expenses, and any future legal expenses that will be incurred in defense of our intellectual property, have been expensed as incurred to selling, general and administrative expense in our consolidated statements of operations. We continue to seek resolution of these infringement claims, and we intend to continue to protect, defend and extend our intellectual property rights in our technology vigorously and aggressively.

Patents and Patent Applications

As of December 31, 2021, our patent portfolio included 12 patent families that, collectively, consisted of five issued U.S. patents, 55 granted foreign patents (variously in Australia, Canada, China, Japan, France, Germany, Italy, Spain, and United Kingdom), and 20 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. There were 10 granted patents, including one U.S. patent, directed to our novel HTG EdgeSeq methods in the portfolio as of December 31, 2021. The HTG EdgeSeq method patents will expire in April 2032. Our patent portfolio includes five applications directed towards our direct-target sequencing HTG EdgeSeq methods, five applications directed towards our methods of subtyping DLBCL, and seven applications directed towards our methods of 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, including short term available-for-sale securities, 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 LDTs, which they may develop using consumables they purchase from us. 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. 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 CE/IVD marked products must continue to meet the requirements of IVDD for commercialization in the EU until the requirements of IVDR take effect on May 26, 2022. At this time we do not anticipate moving to the requirements of IVDR for our existing CE/IVD marked products. As such, these products will no longer be available other than for research use only after that date.

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 laws, 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) which 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, which 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, which 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), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; 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. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. However, it is possible that the ACA will be subject to judicial or Congressional challenges in the future. Congress and the Biden administration are considering various health reform measures. Further, 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.

Human Capital

Our ability to identify and recruit strong candidates into our company and to retain and develop current talent within our organization 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. We believe our culture and commitment to our employees result in the attraction and retention of qualified talent, while providing significant value to our company and its stockholders. As of December 31, 2021, we had 87 full-time and one part-time employee, of which 15 are employed in administration, 21 in manufacturing and operations, 27 in research and development, three in regulatory and quality affairs, and 22 in direct sales and marketing. Of these employees, six 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.

Where You Can Find Additional Information

We make available free of charge through our investor relations website, www.htgmolecular.com, our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by contacting Investor Relations, HTG Molecular Diagnostics, Inc., 3430 E. Global Loop, Tucson, Arizona 85706, e-mail: info@htgmolecular.com. Our Internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

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 $17.1 million and $20.9 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $208.3 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, the commercialization of our HTG EdgeSeq platform and proprietary consumables and advancement of our HTG Therapeutics business unit. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products and services. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products and services, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

We 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 cannot be certain that our existing resources will be sufficient to fund our planned operations and expenditures for at least the next 12 months from the date of this report. Potentially changing circumstances, including those related to COVID-19, may also result in the depletion of our capital resources more rapidly than we currently anticipate. These circumstances raise substantial doubt about our ability to continue as a going concern. We will need to obtain additional funds to finance our operations. 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. 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the current Russia-Ukraine conflict has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have

adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

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 commercially launched our HTG Transcriptome Panel in August 2021. Although we believe that the HTG Transcriptome Panel will be a foundational product for RUO profiling, future companion diagnostics and potential proprietary diagnostic products and will allow us to further expand our product offerings outside of oncology and autoimmune and into additional markets such as transplant and diabetes, we have only recently initiated commercial sales of this panel and it may not have the commercial success that we anticipate or hope for, or that it will allow us to expand our product offerings. 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, profiling and 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.

COVID-19 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 COVID-19.

COVID-19 has caused several states and countries to implement quarantines and/or significant restrictions on travel. In addition, affected regions, including several states within the United States, have previously implemented work restrictions that limited many employees from going to work. Moreover, COVID-19 has resulted in business closures and a substantial reduction in economic activity in the United States and worldwide. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of restrictions will be imposed in the future, notwithstanding increasing vaccination and immunity levels.

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, COVID-19 had a negative impact on our product and product-related services revenue in 2020 and 2021. While we have seen some recovery in customers returning to work, we believe this period of reduced revenue will continue into 2022 as many customers have not returned to historical operating levels, are not yet allowing visitors on site at their facilities or have not resumed previously planned studies. The extent of this impact is likely to vary from customer to customer depending upon how they are or have been 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.

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 further COVID-19 outbreaks will continue to impact our workforce, supply chains or distribution networks or otherwise impact our ability to conduct sample processing services in our laboratory or to travel to customer facilities for commercial or support functions in the future. Governmental mandates may require forced shutdowns of our facilities for extended or indefinite periods. Pandemic outbreaks, including the COVID-19, 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 COVID-19 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 effects of ongoing or future health epidemics on our business remain uncertain and subject to change. While we do not know the full extent of potential delays or impacts on the global economy, 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, conflicts (including the current Russia-Ukraine conflict), 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.

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

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

Numerous other factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, two customers accounted for 20% and 10% of our revenue for the year ended December 31, 2021. The two largest customers accounted for 18%, and 17% of our accounts receivable balance as of December 31, 2021. The third and fourth largest customers accounted for 10% each of our accounts receivable balance as of December 31, 2021. 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 COVID-19. 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.

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. 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* EU. These products may be used by customers for diagnostic purposes in Europe. With the EU transition to IVD Medical Device Regulation in May 2022, we would need to comply with these requirements in order to remain on the EU market other than research use only. 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 commercially launched our HTG Transcriptome Panel in August 2021. Although we believe that the HTG Transcriptome Panel will be a foundational product for RUO profiling, future companion diagnostics and potential proprietary diagnostic products, and will allow us to further expand our product offerings outside of oncology and autoimmune and into additional markets such as transplant and diabetes, we have only recently initiated commercial sales of this panel and it may not have the commercial success that we anticipate or hope for, or that it will allow us to expand our product offerings. In July 2021, we formed a new drug discovery business unit, HTG Therapeutics, which is expected to use our HTG Transcriptome Panel and an epitranscriptome profiling technology to profile RNA modifications, and we expect that, by leveraging these profiling technologies earlier in the drug discovery process, HTG Therapeutics will generate lead compounds faster, and with potentially more favorable efficacy and toxicity profiles. However, there can be no assurance that HTG Therapeutics will be able to accomplish these goals or will otherwise be successful. In addition, we are building a full machine learning-based chemical library design platform, which is expected to better predict the binding properties of a drug candidate to its target. If we are unsuccessful at developing this full machine learning-based chemical library design platform, or it, HTG Therapeutics or our HTG Transcriptome Panel do not provide the benefits that we anticipate, our future revenue opportunities will be limited.

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 development and 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. With the EU transition to IVD Medical Device Regulation in May 2022, we would need to comply with these requirements in order to remain on the EU market other than research use only. While our current ex-U.S. strategy is to focus our efforts on the RUO market, in the event we want to expand our ex-U.S. business opportunities outside of research use only there would likely be additional clinical validations and certifications that we would need to obtain and there can be no assurance that we would be able obtain to obtain any such validations or certifications on a timely basis, or at all. In addition, 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.

Our HTG Therapeutics business strategy may require significant investments in working capital and may not generate any revenue.

In July 2021, we formed a new drug discovery business unit, HTG Therapeutics. This business unit is expected to use our HTG Transcriptome Panel and an epitranscriptome profiling technology evolved from our original HTG EdgeSeq technology, HTG EpiEdgeSeq, to profile RNA modifications. By leveraging these profiling technologies earlier in the drug discovery process, our objective is for HTG Therapeutics to generate lead compounds faster, and with potentially more favorable efficacy and toxicity profiles, with the ultimate goal of generating interest from pharmaceutical companies that results in research or licensing collaborations for, or acquisitions of, these compounds. However, while we have hired experienced employees and added drug development depth to our Board of Directors, as a company we have no prior experience with drug discovery and development and may not be successful in this endeavor. Moreover, drug discovery and development is expensive and will require investments in working capital by us that may be significant. Even if we are successful in partnering for one or more early-stage drug discovery programs with a pharmaceutical company, we will need to expend potentially significant capital resources on these programs prior to any such partnering, and potentially after, and there can be no assurance that we will generate meaningful revenue from these programs. We will need to raise additional funds in order to finance the implementation of our HTG Therapeutics business strategy, 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, 2021, approximately 31% of our revenue was generated from sales originated by customers located outside of the United States, compared with 35% for year ended December 31, 2020. 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, including due to the current Russia-Ukraine conflict;
- 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, including our HTG EpiEdgeSeq 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 may 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 Abbott Molecular, Affymetrix, Inc., Agilent Technologies, Inc., BioRad Laboratories, Invite (acquired by Archer Dx, Inc.), Fluidigm Corporation, Illumina, Inc., Luminex Corporation, NanoString Technologies, Inc., Personal Genome Diagnostics (acquired by Labcorp), entities owned and controlled by QIAGEN N.V., Roche Diagnostics, a division of the Roche Group of companies, and Thermo Fisher Scientific, Inc. In addition, there are several other market entrants in the process of developing novel technologies for the life sciences market. 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.

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. In addition, we intend to enter into early-stage drug discovery and development collaborations. However, we cannot guarantee that we will enter into any additional agreements or collaborations. For example, 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 third-party suppliers for certain subcomponents of our products, including a single supplier for one subcomponent of our HTG EdgeSeq instruments.

We rely on third-party suppliers to supply certain subcomponents used in our HTG EdgeSeq instruments and consumables, including a single supplier, In Position Technologies, to produce a certain subcomponent used in our HTG EdgeSeq instruments. While we periodically forecast our needs for these subcomponents, our contracts with these suppliers do not commit them to carry inventory or make available any particular quantities, and the suppliers 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 any of these suppliers, we may not be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, or at all. In addition, we have in the past experienced supply issues, as well as quality control problems such as shipment errors, with certain of our suppliers, and may experience problems in the future. If we should encounter delays or difficulties in securing the quality and quantity of subcomponents we require for our products, our supply chain would be interrupted or our products may not perform as expected, which would adversely affect our sales. A loss or performance failure of any of these suppliers could significantly delay the delivery or impact the performance of our products, 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.

Developing companion diagnostic products may require large investments in working capital and may not generate any revenue.

A 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.

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 could cause a material adverse effect on our financial position.

Pursuant to the terms of the NuvoGen obligation, we have paid NuvoGen $10.6 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.

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 Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax 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, 2021, we had federal net operating loss carryforwards ("NOLs") to offset future taxable income of $194.0 million, of which $121.8 million will begin to expire after 2023 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 current law, our federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely but the deductibility of these federal NOLs in tax years beginning after December 31, 2021 is limited to 80% of taxable income. 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. However, we cannot guarantee 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.

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 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. Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our systems and networks or the systems and networks of third parties that support us and our services. Additionally, due to the COVID-19 pandemic and our remote workforce, there is an increased risk to our information technology assets and data. 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.

Despite the security controls we have in place, cyber events are very difficult to avoid. 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 cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse impacts arising out of our privacy and security practices, processing or security incidents we may experience, or that such coverage will continue to be available on commercially reasonable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements) could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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. The CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. We may be subject to additional U.S. privacy regulations in the future, including the Virginia Consumer Data Protection Act, or VCDPA, and the Colorado Privacy Act, both of which become effective in 2023. New legislation proposed or enacted in a number of states may impose, or have the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. To the extent multiple state-level laws are introduced with inconsistent or conflicting standards and there is no federal law to preempt such laws, compliance with such laws could be difficult and costly to achieve.

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 Quality Systems Regulations ("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 required 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 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. 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, other healthcare practitioners (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as applicable manufacturers and group purchasing organizations to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members.
- State law equivalents of each of the above federal laws, such as anti-kickback, self-referral, and false claims laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the Federal Government that otherwise restricts payments that may be made to healthcare providers; state laws that require device manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

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

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

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

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

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

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

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

On April 1, 2014, the Protecting Access to Medicare Act of 2014 ("PAMA") was signed into law, which, among other things, significantly 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 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). Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2023 and March 31, 2023, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2024 to 2026 CLFS rates. 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. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES

Act"), the statutory phase-in of the payment reductions has been extended through 2024, with a 0% reduction cap for 2021-2022, and a 15% reduction cap for 2023 through 2025. It is still too early to predict the full impact on reimbursement for our products in development.

Also, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS was required to publicly report payment for the tests. 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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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 have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, 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 considered legislation to 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, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (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". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges 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, will stay in effect through 2031 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, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Further, Congress and the Biden administration are considering additional health reform measures. 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," "qNPA," "HTG Transcriptome Panel" and "HTG EpiEdgeSeq" 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 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 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 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 2022. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Our Common Stock

We expect that our stock price will fluctuate significantly.

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

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new products, significant contracts, commercial relationships or capital commitments;
- failure to obtain or delays in obtaining product approvals or clearances from the FDA or foreign regulators;
- adverse regulatory or coverage and reimbursement announcements;
- issuance of new or changed securities analysts' reports or recommendations for our stock;

- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the life sciences and molecular diagnostics markets;
- manufacturing disruptions;
- any future sales of our common stock or other securities;
- any change to the composition of our Board of Directors, executive officers or key personnel;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from Nasdaq;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic conditions and slow or negative growth of our markets
- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, such as the recent Russian invasion of Ukraine as well as continued and any new sanctions against Russia by, among others, the United States and the European Union, which restrict a wide range of trade and financial dealings with Russia and Russia parties, public health issues including health epidemics or pandemics, such as COVID-19, and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, any of which could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability; 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. COVID-19, 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"), we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Pursuant to our 2021 Inducement Plan ("Inducement Plan"), we are authorized to grant up to 300,000 shares to new employees as inducements material to such new employees entering into employment with us. The number of shares which may be granted under the Inducement Plan may be increased in the future by our board of directors without stockholder approval. In addition, our amended and restated 2014 Employee Stock Purchase Plan ("ESPP") authorizes us to offer, sell and issue shares to our employees. 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

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 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.

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 and again in September 2021 to extend the terms of the leases for three years, through January 31, 2025. The lease extension allows for an additional extension of two 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 $24,000 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 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. Although we anticipate that we will continue to incur legal fees in the coming periods to defend our intellectual property rights, we do not believe that there are any claims or actions pending against us currently, the ultimate disposition of which could have a material adverse effect on our consolidated results of operation, financial condition or cash flows.

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, 2022, the last reported sale price of our common stock was $1.99 per share.

Holders

As of March 15, 2022, there were approximately 113 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. [Reserved].

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 have been adjusted to reflect the reverse stock split for all periods and dates presented.

Overview

We are a life sciences company advancing precision medicine through our innovative transcriptome-wide profiling technology. Building on more than a decade of pioneering innovation and partnerships with biopharma leaders and major academic institutes, our proprietary HTG EdgeSeq RNA platform technology is designed to make the development of life science tools and diagnostics more effective and efficient and to unlock a differentiated and disruptive approach to drug discovery.

Our product and service solutions enable 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 system, 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. 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 existing 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. We believe that our target customers and collaborators desire high quality molecular profiling data in a multiplexed panel format from increasingly smaller and less invasive samples, providing our customers and collaborators with the option to analyze such data locally to minimize turnaround time and cost.

Biopharmaceutical companies are continually working to improve their drug development processes and the efficacy and safety 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.

In addition, we believe that our newly formed drug discovery business unit will allow us to leverage our HTP and epitranscriptome profiling technologies and apply them early in the drug discovery process in conjunction with our machine learning-based chemical library design platform, to ultimately yield de-risked drug candidate molecules with greater potential for clinical success.

We believe our future financial performance will be driven by continued adoption and utilization of our HTG EdgeSeq instruments and consumables, and an overall increase in the number and type of customers using our technology. As such, 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. Total active customers and active installed base reflect customers and instruments that have generated revenue for the Company within the last 12 months. To be included in our active programs metric, a program needs to be associated with a pharma sponsored clinical trial, be traceable to a program on clinicaltrials.gov and have generated revenue for the Company within the last 12 months. As of December 31, 2021, we had 82 active customers, 62 active programs and 51 instruments actively producing revenue in our installed base.

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.

2021 Highlights and Recent Developments

Our development efforts over the past 18 months have been primarily focused on completing feasibility and development of the HTG Transcriptome Panel, including supporting our Early Adopter Program (EAP), where approximately 30 scientific collaborators throughout the U.S. and EU have partnered with us to explore potential applications of the HTG Transcriptome Panel in their research and clinical programs. We expect our EAP collaborators to assist us with customer testimonials, white papers, technical notes and peer-reviewed publications highlighting their use of the HTG Transcriptome Panel and overall experience relative to alternative technologies. The release of the HTG Transcriptome Panel, coupled with our existing whole transcriptome miRNA panel, is expected to allow us to not only continue to expand our position within oncology, but to diversify the use of our panels in other critical markets such as immunology, infectious disease, diabetes, cardiology and neurology. We also expect to focus our future development efforts on the expansion of the sample types available for use with both of these assays, with an initial focus on liquid biopsies.

In the future, we expect to grow our active installed base and drive larger consumable annuities as customer demand for our menu of proprietary panels, including HTP increases, as we 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 as the primary indicators of future commercial adoption and success in our business.

We also announced the formation of our new drug discovery business unit, HTG Therapeutics, in June 2021 with the addition of several highly experienced drug development professionals to our leadership team. HTG Therapeutics intends to utilize our HTP and epitranscriptome profiling technologies, integrated with a machine learning-based chemical library design platform to better-inform the design and selection of drug candidate molecules. Working with our Tucson-based research and development teams, HTG Therapeutics has engaged several external collaborators who are expected to contribute meaningful sample cohorts across multiple disease and therapy areas to identify early candidate molecules with therapeutic promise. These efforts are aimed at the generation of high-quality primary data that we believe could lead to new pharma partnerships in drug discovery and early development by the second half of 2022 and beyond.

COVID-19 and international efforts to control its spread have significantly curtailed the movement of people, goods and services worldwide, including in regions where we sell our products and services and conduct our business over the past year. We experienced a significant slowing in our product and product-related services revenue beginning in March 2020 and throughout the year ended December 31, 2021 due to continued disruptions to our customers' businesses from the pandemic and, in many instances, their prioritization of projects in areas related to COVID-19. In addition, we have experienced extended shipment times and increases in cost of product as ongoing supply chain disruptions have impacted the ability of certain suppliers to produce the materials necessary to build our product and perform our testing services. Despite the impacts of COVID-19 on our revenue and operations, we met all of our key development milestones throughout 2020 and 2021 and have not experienced any substantive manufacturing delays from raw material shortages. While most of our customers have now reopened their facilities, at least on a limited basis, it remains unknown whether COVID-19 will continue to materially impact our financial condition, liquidity and results of operations in future periods due to further shutdowns, social distancing measures or illness.

In March 2022, we entered into a Securities Purchase Agreement (the "March 2022 Purchase Agreement") with a single investor pursuant to which we agreed to issue to the investor 3,244,987 units at a price of $2.312 per unit (less $0.001 for each pre-funded warrant purchased in lieu of a share of common stock) for gross proceeds, before deducting the placement agent fees and other estimated fees and expenses, of approximately $7.5 million. Each unit consists of one share of common stock (or one pre-funded warrant in lieu thereof), a common warrant to purchase one share of our common stock with a term of 24 months from the issuance date, and a common warrant to purchase one share of our common stock with a term of 66 months from the issuance date. Each of the common warrants is exercisable six months following the closing date and has an exercise price of $2.062 per share. Each pre-funded warrant has an exercise price of $0.001 per share and does not expire until exercised in full.

Financial Operations Overview and Consolidated Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

	Years Ended December 31,		Change	
	2021	2020	$	%
Revenue:				
Product and product-related services	$ 8,906,828	$ 7,890,854	$ 1,015,974	13%
Collaborative development services	—	658,010	(658,010)	(100%)
Total revenue	8,906,828	8,548,864	357,964	4%
Operating expenses:				
Cost of product and product-related services revenue	4,094,980	3,991,532	103,448	3%
Selling, general and administrative	16,546,740	18,063,064	(1,516,324)	(8%)
Research and development	6,088,934	6,079,907	9,027	0%
Total operating expenses	26,730,654	28,134,503	(1,403,849)	(5%)
Operating loss	(17,823,826)	(19,585,639)	1,761,813	(9%)
Gain on forgiveness of PPP Loan	1,735,792	—	1,735,792	100%
Loss on extinguishment of MidCap Credit Facility and QNAH Convertible Note	—	(522,394)	522,394	(100%)
Other income (expense), net	(1,034,661)	(747,770)	(286,891)	38%
Net loss before income taxes	$ (17,122,695)	$ (20,855,803)	$ 3,733,108	(18%)

Revenue

Our product and product-related services revenue is generated through the sale of our profiling instruments and consumables, sample processing services and custom assay design services to biopharmaceutical companies, academic research centers and molecular testing laboratories.

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

We have also previously generated collaborative development services revenue through three statements of work entered into under our prior Master Assay Development, Commercialization and Manufacturing Agreement (the "Governing Agreement") with QIAGEN Manchester Limited ("QML"). Under these agreements, we and QML combined our technological and commercial strengths to offer biopharmaceutical companies a complete NGS-based solution for the development, manufacture and commercialization of companion diagnostic assays in support of and in conjunction with, biopharmaceutical companies' drug development programs. Remaining agreed upon procedures associated with these statements of work were completed in the prior year and no additional collaborative development services programs have been entered into as of December 31, 2021. Although we continue to seek potential, new customer collaborations, we currently do not anticipate additional revenue from existing or new collaborative development services programs in 2022.

Total revenue increased by 4% to $8.9 million for the year ended December 31, 2021 compared with total revenue of $8.5 million for the year ended December 31, 2020. While we continued to experience slowing as a result of the COVID-19 pandemic throughout the first half of 2021, we began to see the majority of our customers resume planned studies in the second half of the year.

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, increased by 13% to $8.9 million for the year ended December 31, 2021 compared with $7.9 million for the year ended December 31, 2020, and was comprised of the following:

	Years Ended December 31,		Change	
	2021	2020	$	%
Product revenue:				
Instruments	$ 1,385,665	$ 869,035	$ 516,630	59%
Consumables	3,786,923	3,030,612	756,311	25%
Total product revenue	5,172,588	3,899,647	1,272,941	33%
Product-related services revenue:				
Custom RUO assay design	48,350	1,393,316	(1,344,966)	(97%)
RUO sample processing	3,685,890	2,597,891	1,087,999	42%
Total product-related services revenue	3,734,240	3,991,207	(256,967)	(6%)
Total product and product-related services revenue	$ 8,906,828	$ 7,890,854	$ 1,015,974	13%

Product revenue, which includes gene expression profiling revenue generated through the sale of our HTG EdgeSeq instruments and consumables, increased by 33% to $5.2 million for the year ended December 31, 2021 compared with $3.9 million for the year ended December 31, 2020. This increase primarily reflects additional instrument placements made during the year with biopharmaceutical companies and academic medical centers when compared to the prior year, when most of our customers had closed their laboratories due to COVID-19. In addition, consumables product revenue for the year ended December 31, 2021 included revenue recognized from the sale of HTG Transcriptome Panel consumables. Revenue from the sale of the HTG Transcriptome Panel represented 34% of our consumables revenue for the year ended December 31, 2021. Product revenue represented 58% and 46% of our total revenue for the years ended December 31, 2021 and 2020, respectively.

Product-related services revenue, consisting of RUO sample processing using HTG EdgeSeq instruments and consumables in our VERI/O laboratory and custom RUO assay development services, decreased by 6% to $3.7 million for the year ended December 31, 2021 compared with $4.0 million for the year ended December 31, 2020. The decrease in product-related service revenue is a result of an increase in RUO sample processing revenue of 42% to $3.7 million compared to $2.6 million for the years ended December 31, 2021 and 2020, respectively, offset by a 97% decrease in custom RUO assay design services to $48,000 compared to $1.4 million for the years ended December 31, 2021 and 2020, respectively. Product-related services revenue represented 42% and 47% of our total revenue for the years ended December 31, 2021 and 2020, respectively.

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 increased by 3% to $4.1 million for the year ended December 31, 2021 compared with $4.0 million for the year ended December 31, 2020. This increase in cost of product and product-related services revenue for the year ended December 31, 2021 compared with the same period in 2020 primarily reflects an increase in product and product-related services revenue offset by a reduction of compensation expense in our cost of product and product-related services from Employee Retention Credits (“ERC”) secured in the first three quarters of 2021 in accordance with the Federal Consolidated Appropriations Act.

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 8% to $16.5 million for the year ended December 31, 2021 compared with $18.1 million for the year ended December 31, 2020. This decrease in selling, general and administrative expense for the year ended December 31, 2021 compared with the same period in 2020 reflects a decrease in stock-based and other compensation-related expense items, as well as ERC benefits secured in the first three quarters of 2021. Offsetting the reduction in compensation-related expense items, was an increase in legal costs related to protecting our intellectual property. We anticipate these higher legal costs to protect and defend our intellectual property will continue into 2022.

Research and development expenses

Research and development expenses represent costs to develop new proprietary panels and technologies, including the technology related to our HTG Therapeutics business unit, costs to continue improving and expanding the utility of our HTG EdgeSeq technology, and amounts incurred to perform collaborative development services. These expenses include payroll and related expenses, consulting expenses, laboratory supplies, facilities and equipment. Research and development costs are expensed as incurred. Research and development expenses were $6.1 million for both of the years ended December 31, 2021 and 2020, and included $0 and $0.5 million of costs relating to our collaborative development services revenue for the years ended December 31, 2021 and 2020, respectively. Despite the decrease in collaborative development services expense year over year, research and development expense remained consistent with prior year as a result of approximately $1.4 million of technology, consulting and personnel investments made for the year ended December 31, 2021 relating to HTG Therapeutics.

Other income (expense)

In addition to interest expense and income related to our debt, contractual obligations and available-for-sale securities investments, we have recorded other non-operating activities in our consolidated statements of operations for both the years ended December 31, 2021 and 2020. Upon receipt in of the notification that the PPP Loan and related accrued interest had been forgiven by the U.S. Small Business Administration and that the PPP Loan note had been cancelled in May 2021, we reversed the liabilities related to the PPP Loan and recorded a gain on forgiveness of PPP Loan of approximately $1.7 million. In 2020, as a result of the repayment of all amounts and fees outstanding under the MidCap Credit Facility and the QNAH Convertible Note with proceeds from the SVB Term Loan, we recorded a loss on extinguishment of MidCap Credit Facility and QNAH Convertible Note of approximately $0.5 million.

As of both December 31, 2021 and 2020, we had outstanding obligations due to NuvoGen under an asset purchase agreement and an SVB Term Loan obligation. 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, 2021 and 2020. Interest income related to our available-for-sale debt securities investments included in other income (expense) in the consolidated statements of operations decreased by 88% to $30,000 for the year ended December 31, 2021 as compared with $0.3 million for the year ended December 31, 2020 due to a decrease of maturities of available-for-sale securities combined with lower interest rates in 2021.

Cash Flows for the Years Ended December 31, 2021 and 2020

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

	Years Ended December 31,		Change	
	2021	2020	$	%
Net cash provided by (used in):				
Operating activities	$ (16,508,554)	$ (16,292,377)	(216,177)	1%
Investing activities	(6,664,744)	18,731,107	(25,395,851)	(136%)
Financing activities	10,391,622	9,049,478	1,342,144	15%
Effect of exchange rate on cash	(16,186)	19,609	(35,795)	(183%)
Increase (decrease) in cash, cash equivalents and restricted cash	$ (12,797,862)	$ 11,507,817	(24,305,679)	(211%)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 increased by 1% to $16.5 million compared with $16.3 million for the year ended December 31, 2020. This increase for the year ended December 31, 2021 reflected (i) the net loss of $17.1 million and (ii) net non-cash items of $1.6 million consisting primarily of the gain on the forgiveness of our PPP loan of $1.7 million, stock-based compensation expense of $1.3 million, depreciation and amortization expense of $0.7 million, amortization of loan discount and issuance costs of $0.5 million, non-cash operating lease expense of $0.5 million and loss on abandonment and disposal of assets of $0.2 million; and (iii) a net cash outflow from changes in balances of operating assets and liabilities of $1.0 million.

Net cash used in operating activities for the year ended December 31, 2020 was $16.3 million and 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.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 increased by 136% to $6.7 million compared with net cash provided by investing activities of $18.7 million for the year ended December 31, 2020. Net cash used in investing activities for the year ended December 31, 2021 consisted primarily of purchases of available-for-sale securities of $18.6 million, partially offset by the maturity of $12.6 million of the available-for-sale securities and the purchase of $0.6 million of laboratory equipment and other fixed assets during the year.

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.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 increased by 15% to $10.4 million compared with $9.0 million for the year ended December 31, 2020. This activity for the year ended December 31, 2021 consisted primarily of $10.7 million in net proceeds from sales of our common stock in an “at the market offering” and $0.9 million in proceeds from our stock purchase agreement (the “LP Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), partially offset by $0.5 million of payments made on our outstanding NuvoGen obligation, and $0.7 million of payments made on our 2020 and 2021 Insurance Notes.

Net cash provided by financing activities for the year ended December 31, 2020 was $9.0 million. 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

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, 2021, we had $21.9 million in cash, cash equivalents and investments in short-term available-for-sale securities, and current liabilities of $9.9 million. As of December 31, 2021, we also had approximately $10.1 million of long-term liabilities outstanding, relating to our SVB Term Loan, our NuvoGen obligation, and our financing and operating leases.

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, 2021. 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, 2021, 352,004 shares of our common stock have been sold to Lincoln Park under the LP Purchase Agreement for aggregate proceeds of $1.9 million. Pursuant to the March 2022 Purchase Agreement, we may not sell any shares under the LP Purchase Agreement for the remainder of the 36-month term of the LP Purchase Agreement.

In April 2020, we received the proceeds from the PPP Loan in the amount of $1.7 million from SVB, as lender, pursuant to the Paycheck Protection Program of the CARES Act. In May 2021, we received notification from SVB that the PPP Loan and related accrued interest, totaling $1,735,792, was forgiven in full by the U.S. Small Business Administration, and the PPP Loan note was canceled.

In June 2020, we entered into a Loan and Security Agreement (the "Loan Agreement") for an asset-secured loan in the principal amount of $10.0 million with Silicon Valley Bank ("SVB"), as lender (the "SVB Term Loan"). The proceeds from the SVB Term Loan were fully funded on 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 our 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 and Security Agreement) and 5.75% and originally required interest-only payments payable monthly in arrears through June 30, 2021. This interest-only period has been extended for an additional six months as a result of the Company's achievement of the equity milestone defined in the Loan Agreement. The extended 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, including investments in short term available-for-sale securities, under the Loan Agreement (see Note 8 to our consolidated financial statements included elsewhere in this report). We expect that we could be out of compliance with this unrestricted minimum cash covenant as early as mid-2022 unless we are successful in raising additional equity capital or are able to amend the covenant with the bank. 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 commercial 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, ceases 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.

Contractual Obligations, Commitments and Material Cash Requirements

We have had recurring operating losses and negative cash flows from operations since our inception and have an accumulated deficit of $208.3 million as of December 31, 2021. As of December 31, 2021, we had cash, cash equivalents and investments in short-term available-for-sale securities of $21.9 million and had current liabilities of $9.9 million. As of December 31, 2021, we also had approximately $10.1 million of long-term liabilities outstanding, relating to our SVB Term Loan, our NuvoGen obligation, and our financing and operating leases.

We cannot be certain that our existing resources will be sufficient to fund our planned operations and expenditures for at least the next 12 months from issuance of these consolidated financial statements. Potentially changing circumstances, including those related to COVID-19, may also result in the depletion of our capital resources more rapidly than we currently anticipate. These circumstances raise substantial doubt about our ability to continue as a going concern.

Our primary capital needs, including contractual obligations and commitments, which are subject to change, include:

- Debt Obligations – As of December 31, 2021, our outstanding debt balance was $10.3 million. See Note 8, "Debt Obligations" within our consolidated financial statements for further detail of our debt and the timing of expected future payments.
- NuvoGen Obligation – As of December 31, 2021, our NuvoGen obligation balance was $4.4 million. See Note 10, "Other Agreements" within our consolidated financial statements for further detail and the timing of expected future payments.
- Operating Leases – As of December 31, 2021, our contractual commitment for operating leases was $1.5 million. See Note 11, "Leases" within our consolidated financial statements for further detail of our lease obligations and the timing of expected future payments, including a four-year maturity schedule.
- Planned costs to operating our business, including amounts required to fund working capital and capital expenditures;
- Support of commercialization efforts related to our current and future products; and
- Continued advancement of research and development efforts, including those related to our planned transcriptome panel.

Until our revenue reaches a level sufficient to support self-sustaining cash flows, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, or other capital sources which may include strategic collaborations, licensing arrangements or other arrangements with third parties. 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 extent to which we acquire or invest in businesses, products and technologies.

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

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 Critical Accounting 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. Critical accounting policies and estimates are those that we consider most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and estimates include those related to revenue recognition, stock-based compensation expense, inventory valuation, fair value measurements and income taxes. 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 year ended December 31, 2020, 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 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, 2021 and 2020, 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, 2021 and 2020, 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 and negative operating cash flows 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.

Reserve for Excess and Obsolete Inventory

As more fully described in Notes 2 and 3 to the consolidated financial statements, the Company's consolidated inventory balance was approximately $2.7 million at December 31, 2021. 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. The Company reserves its inventory for estimated obsolescence or inventory in excess of expected sales or unmarketable inventory, based upon assumptions about future demand and market conditions.

We identified the valuation of inventories with respect to excess and obsolete inventory as a critical audit matter. Specifically, the determination of the reserve for excess and obsolete inventory requires management to make judgments and assumptions about the

future usage and sales of inventory. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address this matter.

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

- Evaluating management’s process for establishing a reserve for excess and obsolete inventory by understanding inventory management practices and assessing the appropriateness of management’s estimation.
- Assessing whether any known or knowable factors occurred subsequent to year end that impact management’s forecast of future inventory usage.
- Evaluating the reasonableness of certain management forecasts by comparing forecasted sales for the current period to actual sales for the current period and quantifying the impact of any variations on future forecasts.

/s/ BDO USA, LLP

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

Los Angeles, California
March 29, 2022

HTG Molecular Diagnostics, Inc.
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 9,599,950	$ 22,397,812
Short-term investments available-for-sale, at fair value	12,343,456	6,298,075
Accounts receivable, net of allowance of $20,315 at December 31, 2021 and $0 at December 31, 2020	2,092,466	1,588,767
Inventory, net of allowance of $25,306 at December 31, 2021 and $26,052 at December 31, 2020 – current	1,987,753	1,492,126
Prepaid expenses and other	1,163,339	1,094,273
Total current assets	27,186,964	32,871,053
	1,345,361	1,009,097
Property and equipment, net	1,118,886	1,227,402
Other non-current assets	809,476	90,356
Total assets	$ 30,460,687	$ 35,197,908
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,649,440	$ 1,348,762
Accrued liabilities	2,022,569	1,459,878
Contract liabilities – current	124,941	185,083
NuvoGen obligation – current	548,301	512,729
Current portion of long-term debt	5,167,586	3,022,139
Operating lease liabilities – current	413,865	685,220
Other current liabilities	16,808	22,563
Total current liabilities	9,943,510	7,236,374
NuvoGen obligation - non-current, net of discount	3,900,880	4,479,396
Long-term debt, net of current portion, discount and debt issuance costs	5,178,629	8,568,308
Operating lease liabilities - non-current	949,461	368,682
Other non-current liabilities	88,383	60,488
Total liabilities	20,060,863	20,713,248
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, 2021 and 2020	24	24
Common stock, $0.001 par value; 26,666,667 shares authorized at December 31, 2021 and 2020, 7,588,085 shares issued and outstanding at December 31, 2021 and 5,199,997 shares issued and outstanding at December 31, 2020	7,588	5,200
Additional paid-in-capital	218,723,349	205,661,999
Accumulated other comprehensive income	1,894	5,298
Accumulated deficit	(208,333,031)	(191,187,861)
Total stockholders' equity	10,399,824	14,484,660
Total liabilities and stockholders' equity	$ 30,460,687	$ 35,197,908

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

HTG Molecular Diagnostics, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2021	2020
Revenue:		
Product and product-related services	$ 8,906,828	$ 7,890,854
Collaborative development services	—	658,010
Total revenue	8,906,828	8,548,864
Operating expenses:		
Cost of product and product-related services revenue	4,094,980	3,991,532
Selling, general and administrative	16,546,740	18,063,064
Research and development	6,088,934	6,079,907
Total operating expenses	26,730,654	28,134,503
Operating loss	(17,823,826)	(19,585,639)
Other income (expense):		
Interest expense	(1,064,545)	(1,024,774)
Interest income	29,884	254,736
Other income	—	22,268
Gain on forgiveness of PPP Loan	1,735,792	—
Loss on extinguishment of MidCap Credit Facility and QNAH Convertible Note	—	(522,394)
Total other income (expense)	701,131	(1,270,164)
Net loss before income taxes	(17,122,695)	(20,855,803)
Provision for income taxes	(22,475)	(14,415)
Net loss	$ (17,145,170)	$ (20,870,218)
Net loss per share, basic and diluted	$ (2.47)	$ (4.51)
Shares used in computing net loss per share, basic and diluted	6,936,131	4,627,918

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,	
	2021	2020
Net loss	$ (17,145,170)	$ (20,870,218)
Other comprehensive income (loss), net of tax effect:		
Unrealized gain on short-term investments	—	9
Foreign currency translation adjustment	(3,404)	10,253
Total other comprehensive income (loss)	(3,404)	10,262
Comprehensive loss	$ (17,148,574)	$ (20,859,956)

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, 2020	-	$ -	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 awards	—	—	(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
Stock-based compensation expense	—	—	—	—	1,317,351	—	—	1,317,351
Release of restricted stock awards	—	—	4,529	4	—	—	—	4
Net share settlement of restricted stock awards	—	—	(611)	—	(3,239)	—	—	(3,239)
Employee stock purchase plan expense	—	—	—	—	57,669	—	—	57,669
Stock issued under stock purchase plans	—	—	33,963	34	125,794	—	—	125,828
Issuance of common stock from ATM offering, net of commissions of approximately $0.3 million	—	—	2,050,879	2,051	10,663,768	—	—	10,665,819
Issuance of common stock in connection with LP Purchase Agreement	—	—	154,372	154	899,826	—	—	899,980
Exercise of pre-funded warrants	—	—	144,881	145	(145)	—	—	—
Exercise of stock options	—	—	75	—	326	—	—	326
Net loss	—	—	—	—	—	—	(17,145,170)	(17,145,170)
Foreign currency translation adjustment	—	—	—	—	—	(3,404)	—	(3,404)
Balance at December 31, 2021	23,770	$ 24	7,588,085	$ 7,588	$ 218,723,349	$ 1,894	$ (208,333,031)	$ 10,399,824

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,	
	2021	2020
Operating activities		
Net loss	$ (17,145,170)	$ (20,870,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	721,246	1,346,560
Accretion of discount on NuvoGen obligation	(12,288)	(12,936)
Provision for excess inventory	174,589	53,298
Amortization of QNAH Convertible Note issuance costs	—	6,505
Amortization of MidCap Credit Facility discount and issuance costs	—	101,482
Amortization of SVB Term Loan discount and issuance costs	470,281	243,541
Stock-based compensation expense	1,317,355	1,584,785
Employee stock purchase plan expense	57,669	21,186
Bad debt expense	20,315	—
Non-cash operating lease expense	458,001	629,501
Accrued interest on available-for-sale securities investments	(25,018)	(72,503)
Stock compensation expense in connection with LP Purchase Agreement	—	205,538
Gain on forgiveness of PPP Loan	(1,735,792)	—
Loss on extinguishment of Midcap Credit Facility and QNAH Convertible Note	—	522,394
Loss on abandonment and disposal of assets, net	180,008	105,063
Changes in operating assets and liabilities:		
Accounts receivable	(805,736)	1,575,409
Inventory	(1,365,384)	(256,940)
Prepaid expenses and other	619,226	284,921
Deferred offering costs	—	140,320
Accounts payable	453,337	(23,801)
Accrued liabilities	616,447	(409,035)
Contract liabilities	(38,314)	(683,716)
Operating lease liabilities	(469,326)	(783,731)
Net cash used in operating activities	(16,508,554)	(16,292,377)
Investing activities		
Purchase of property and equipment	(644,381)	(453,552)
Maturities of available-for-sale securities	12,600,000	31,650,000
Purchase of available-for-sale securities	(18,620,363)	(12,465,341)
Net cash (used in) provided by investing activities	(6,664,744)	18,731,107
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 ATM Offering, net of commissions of $0.3 million	10,665,819	7,545,838
Proceeds from LP Purchase Agreement	899,980	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	(530,656)	(645,949)
Proceeds from exercise of pre-funded warrants	—	31,768
Payments on financing leases	(22,563)	(41,134)
Proceeds from exercise of stock options	326	—
Taxes paid for net share settlement of restricted stock awards	(3,239)	(14,049)
Cash in lieu of fractional shares related to reverse stock split	—	(560)
Proceeds from shares purchased under stock purchase plans	125,828	40,976
Payments on 2021 and 2020 Insurance Notes	(743,873)	(570,096)
Net cash provided by financing activities	10,391,622	9,049,478
Effect of exchange rates on cash	(16,186)	19,609
Increase (decrease) in cash, cash equivalents and restricted cash	(12,797,862)	11,507,817
Cash, cash equivalents and restricted cash at beginning of year	22,397,812	10,889,995
Cash and cash equivalents at end of year	$ 9,599,950	$ 22,397,812
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
Issuance of common stock from cashless exercise of pre-funded warrants	145	—
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	1,302,457	447,987
Carrying value of demonstration units transferred from property and equipment to inventory	16,128	18,817
2021 and 2020 Insurance Notes issued for insurance premiums	746,360	735,195
Reclassification of contract liability to refund liability	—	281,722
Disposal of fully depreciated assets	635,870	—
Gain on forgiveness of PPP Loan	1,735,792	—
Supplemental cash flow information		
Cash paid for interest	$ 599,922	$ 869,857
Cash paid for taxes	12,665	17,514

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 life science company whose mission is to advance precision medicine through its innovative transcriptome-wide profiling technology. The Company derives revenue from sales of its HTG EdgeSeq system and integrated next-generation sequencing-based ("NGS-based") HTG EdgeSeq assays, from sample processing services performed in its VERI/O laboratory and from collaborative development services.

The Company operates in one segment and its customers and distributors are geographically located primarily in the United States and Europe. For sales to distributors, their locations may be different from the locations of the end customers. For the year ended December 31, 2021, approximately 31% of the Company's revenue was generated from sales originated by customers located outside of the United States, compared with 35% for the year ended December 31, 2020.

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, this impact will continue to be seen at some level at least through the first half of 2022. 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 not experienced delays in its development efforts because of stay-at-home orders despite its efforts to prioritize the safety of its employees during this pandemic. In addition, the impact of the COVID-19 pandemic on the Company's ability to source raw materials and other supplies has not been significant to date. However, a change in or loss of suppliers or other supply chain or distribution network partners due to the ongoing impacts of the pandemic on the global economy could adversely affect the Company's business and the businesses of its vendors, partners and customers, and could result in future reductions in sales and operating results.

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.

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, 2021 and 2020.

Going Concern and Liquidity

Management has assessed the Company's ability to continue as a going concern within one year of issuance of these consolidated financial statements. The accompanying 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 $208.3 million as of December 31, 2021. As of December 31, 2021, the Company had working capital of $17.2 million and long-term liabilities of $10.1 million. The Company's liability balances consist primarily of its debt obligations, including an asset-secured loan with Silicon Valley Bank ("SVB") (the "SVB Term Loan") (see Note 8), as well as an obligation to NuvoGen Research, LLC (the "NuvoGen obligation") (see Note 10). Potentially changing circumstances, including COVID-19 uncertainties, may result in the depletion of the Company's 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 financial covenant in the Loan and Security Agreement for the SVB Term Loan (the "Loan Agreement"). These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying 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 in the Loan Agreement requiring the Company to maintain unrestricted cash, including short term available-for-sale securities, 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. The Company currently expects that it may not be in compliance with this unrestricted cash covenant as early as mid-2022 unless it is successful in raising additional equity capital or is able to amend the covenant with SBV. If the Company breaches the covenant, 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 charge an interest rate of 5% above the otherwise applicable floating rate, accelerate the payment of the SVB Term Loan and ultimately foreclose on the Company's assets.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The Company's estimates include revenue recognition, stock-based compensation expense, bonus and warranty accrual, income tax valuation allowances and reserves, recovery of long-lived assets, lease liability, inventory obsolescence and valuation of inventory, accounts receivable, allowance for doubtful accounts 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 COVID-19 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, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive loss, net of tax, as available-for-sale securities. 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.

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 is 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, 2021, the estimated aggregate fair value of the NuvoGen obligation is approximately $4.6 million, determined using a Monte Carlo simulation with key assumptions including future revenue, volatility, discount and risk-free rates. The estimated fair value of the NuvoGen obligation represents a Level 3 measurement.

Inventory

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. The Company classifies inventory as long-term when the Company expects to utilize the inventory beyond its normal operating cycle.

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, 2021 was $204,638 compared with $50,855 as of December 31, 2020.

Property and Equipment

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, 2021 and 2020.

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 a lease liability for each type of lease, 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 Loan Agreement with SVB were deferred as an asset in the consolidated balance sheets and are being amortized on a straight-line basis to interest expense over the term of the loan. Cost incurred to issue the MidCap Credit and Security Agreement (Revolving Loan) under the Company's credit facility with MidCap Financial Trust (the "MidCap Credit Facility") 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 Facility in June 2020 (see Note 8).

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 research use only ("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 Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("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.

COVID-19 Related Credits and Relief

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to COVID-19. On April 21, 2020, the Company received proceeds from a loan pursuant to the Paycheck Protection Program ("PPP") of the CARES Act (the "PPP Loan") in the amount of $1.7 million from SVB, as lender (see Note 8). The Company applied for full forgiveness of the PPP Loan in October 2020. In May 2021, the Company received notification that the PPP Loan and related accrued interest, totaling $1,735,792, were forgiven by the U.S. Small Business Administration ("SBA"), and that the PPP Loan note had been canceled.

There is no guidance in U.S. GAAP that specifically addresses the accounting by a business entity that obtains a forgivable loan from a government entity. Notwithstanding the absence of specific guidance in U.S. GAAP and given the significant uncertainties related to whether many entities that received loans are qualified for a PPP Loan and would meet the conditions for loan forgiveness, the Company accounted for the PPP Loan as debt in accordance with FASB, ASC 470, *Debt*. Based upon the guidance in ASC 470, the Company recorded a liability for the total amount of the loan upon receipt of the proceeds. Upon confirmation from the SBA that the PPP Loan was forgiven in full and the PPP Loan had been canceled, the Company reversed the liability and related accrued interest and recorded a gain on forgiveness of the PPP Loan.

In December 2020, the Consolidated Appropriations Act (the "Appropriations Act") was signed into law to further address the ongoing impacts of COVID-19. The Appropriations Act introduced several additional potential credits and benefits for employers to consider applying for, including, but not limited to, the ability for employers who have previously obtained a PPP Loan to potentially also qualify for Employee Retention Credits ("ERC"), initially created as part of the CARES Act. The ERC provided a per employee credit to eligible businesses based on a percentage of qualified wages and health insurance benefits paid to employees. The benefit was provided as a refundable payroll tax credit claimed quarterly as a reduction to payroll taxes or cash refunds. The initial credit available was equal to 50% of qualified wages paid to employees during a quarter, capped at $10,000 of qualified wages per employee through December 31, 2021. In March 2021, the American Rescue Plan of 2021 was enacted to, amongst other things, extend and expand ERC benefits through December 31, 2021. In accordance with these additional relief provisions, the tax credit was increased to 70% of qualified wages paid to employees during a quarter, and the limit on qualified wages per employee was increased to $10,000 of qualified wages per quarter. In November 2021, the Infrastructure Investment and Jobs Act was signed into law and ends the employee retention credit early, making wages paid after September 30, 2021, ineligible for the credit.

The Company qualified for certain ERC benefits during the years ended December 31, 2021 and 2020. As there is no guidance in U.S. GAAP that specifically addresses the accounting for the receipt of government assistance similar to the ERC, the Company considered two primary approaches in accounting for the ERC. The first was as government grants, by reference to ASC 958-605, Not-for-Profit-Entities Revenue Recognition, and the other by reference to IAS 20, Accounting for Government Grants and Disclosure of Government Assistance. With reference to IAS 20, the Company considered the following: (1) Under this model, the Company would not recognize government assistance until reasonably sure any conditions attached to the assistance would be met, and the Company would in fact receive the funds. (2) Once the Company was reasonably certain the conditions were met, the Company would then record the earnings impact of the grants over the periods in which the Company recognizes the costs the grants are intended to pay for. These costs should be recognized as expenses. (3) The funds could be recorded as other income or as an offset to related qualifying expenses. The Company has historically offset actual expenses that are reimbursed within the applicable expense line. Because the ERC was intended to reimburse the Company for actual costs incurred during the given period or quarter, the Company determined that it was most reasonable to account for these credits as an offset to the qualifying payroll expenses.

ERC benefits of approximately $1.7 million and $0.5 million were included in operating expenses as an offset to the related compensation costs in the accompanying consolidated statements of operations for the years ended December 31, 2021 and 2020, respectively, as follows:

	Years Ended December 31,	
	2021	2020
Cost of product and product-related services revenue	$ 467,481	$ 108,714
Selling, general and administrative	795,650	229,025
Research and development	444,888	135,744
	$ 1,708,019	$ 473,483

ERC benefits receivable of $0.4 million and $0.5 million were included in prepaid expenses and other in the accompanying consolidated balance sheets as of December 31, 2021 and 2020, respectively. The Company has also applied the guidance in ASU No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance* ("ASU No. 2021-10) retrospectively to the ERC in its financial reporting for the years ended December 31, 2021 and 2020.

Laws and regulations concerning government programs, including the ERC and PPP Loan, are complex and subject to varying interpretations. Claims made under these programs may also be subject to retroactive audit and review. While we do not believe there is a basis for estimation of an audit or recapture risk at this time, there can be no assurance that regulatory authorities will not challenge the Company's claim to the ERC or PPP Loan in a future period.

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. Customers have the option to purchase an extended warranty after the one-year warranty period expires. 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 and other non-current 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, including the technology related to the Company's HTG Therapeutics business units, costs to continue improving and expanding the utility of the HTG EdgeSeq technology, 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. There were no costs associated with collaborative development services included in research and development expense in the consolidated statements of operations for the year ended December 31, 2021.

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 plans.

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 stock purchase 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, 2021 and 2020, 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. Therefore, for income tax positions where it is not more likely than not that a tax benefit will be sustained in a court of last resort, the Company does not recognize a tax benefit in its financial statements.

Foreign Currency Translation and Foreign Currency Transactions

The Company has assets and liabilities, including accounts receivable and accounts payable, which are denominated in currencies other than its functional currency. These 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 income (loss) in the consolidated statements of changes in stockholder's equity.

Comprehensive Income (Loss)

Comprehensive income (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 two customers accounted for 20% and 10% of the Company's total revenue for the year ended December 31, 2021, compared with the top customer accounting for 11% of the Company's total revenue for the year ended December 31, 2020. The largest two customers accounted for approximately 18% and 17% of the Company's accounts receivable as of December 31, 2021. The third and fourth largest customers accounted for approximately 10% each of the Company's accounts receivable as of December 31, 2021. The largest two customers accounted for approximately 9% each of the Company's accounts receivable as of December 31, 2020.

Two vendors accounted for 28% and 16% of the Company's accounts payable as of December 31, 2021, compared with two vendors who accounted for 21% and 20% of the Company's accounts payable as of December 31, 2020.

The Company is also subject to supply chain risks related to the reliance on a single supplier to manufacture a subcomponent used in its HTG EdgeSeq instruments. Although there are a limited number of manufacturers for components of this type, the Company believes that other suppliers could provide similar products on comparable terms. However, a change in or 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 November 2021, the FASB issued ASU No. 2021-10, *Government Assistance (Topic 842): Disclosures by Business Entities about Government Assistance*, which aims to provide increased transparency by requiring business entities to disclose information about certain types of governmental assistance they receive in the notes to the financial statements. The disclosures include information around the nature of the assistance, the related accounting policies used to account for government assistance, the effect of government assistance on the entity's financial statements, and any significant terms and conditions of the agreements, including commitments and contingencies. The new guidance does not apply to transactions that a business accounts for under the income tax, revenue recognition, gain contingency or debt rules. The guidance in ASU 2021-10 was effective for financial statements of all entities for annual periods beginning after December 15, 2021. The Company has early adopted this guidance retrospectively, applying it to all transactions within the scope of the amendments reflected in its consolidated financial statements as of and for the years ended December 31, 2021 and 2020. As the Company's accounting for ERC benefits was in accordance with this guidance, the impact of adoption was limited to disclosures relating to these transactions.

In October 2020, the FASB issued ASC Update ("ASU") No. 2020-10, *Codification Improvements* ("Update No. 2020-10"), which amended a variety of topics in the FASB Codification in order to improve the consistency of the Codification and the application thereof, while leaving GAAP unchanged. Update No. 2020-10 was effective for fiscal years beginning after December 15, 2020 for public business entities. The Company's adoption of this standard on January 1, 2021 did not have a material impact on its consolidated financial statements or related footnote 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 was effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2020. The Company's adoption of this standard on January 1, 2021 did not have a material impact on its consolidated financial statements or related footnote disclosures

Recent Accounting Pronouncements

The following are new FASB ASUs that had not been adopted by the Company as of December 31, 2021:

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 June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses*, which was subsequently amended by ASU 2018-19, ASU 2019-10 and ASU 2020-02, and 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. With the issuance of ASU 2019-10 in November 2019, the standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2022. Early adoption is permitted, including in any interim period. 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 history of minimal 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,	
	2021	2020
Raw materials	$ 1,964,407	$ 1,079,528
Work in process	312,803	147,455
Finished goods	447,145	291,195
Total gross inventory	2,724,355	1,518,178
Less inventory allowance	(25,306)	(26,052)
	$ 2,699,049	$ 1,492,126

Inventory of $2.0 million and $0.7 million was included in inventory – current and other non-current assets, respectively, in the consolidated balance sheets as of December 31, 2021. There was no inventory classified as long-term as of December 31, 2020.

For the years ended December 31, 2021 and 2020, the Company recorded adjustments to the provision for excess inventory of $174,589 and $53,298, respectively. Adjustments in these periods to the allowance for estimated shrinkage, obsolescence and excess inventory and to the inventory reserve 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 as of December 31, 2021 and 2020, respectively, in the fair value hierarchy:

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Asset included in:				
Cash and cash equivalents				
Money market securities	$ 9,083,302	$ —	$ —	$ 9,083,302
Investments available-for-sale at fair value				
Corporate debt securities	—	12,343,456	—	12,343,456
Total	$ 9,083,302	$ 12,343,456	$ —	$ 21,426,758

	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

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, 2021 and 2020.

Level 1 instruments include investments in money market funds. 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, 2021 or 2020 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, 2021. The following is a summary of the Company's available-for-sale securities as of December 31, 2021 and 2020:

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
Corporate debt securities	12,343,456	—	—	12,343,456
Total available-for-sale securities	$ 12,343,456	$ —	$ —	$ 12,343,456

	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

There were no gross unrealized losses relating to the Company's available-for-sale securities investments as of December 31, 2021. The net adjustment to unrealized holding gains on short-term investments, net of tax in other comprehensive income were immaterial for each of the years ended December 31, 2021 and 2020.

Contractual maturities of debt investment securities as of December 31, 2021 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	12,343,456	—	12,343,456
Total available-for-sale securities	$ 12,343,456	$ —	$ 12,343,456

The Company conducts a regular assessment of its debt securities with unrealized losses to determine whether securities have OTTI 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, 2021, there was no OTTI of its available-for-sale securities as of that date.

Note 6. Property and Equipment

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

	December 31,	
	2021	2020
Furniture & fixtures	$ 872,877	$ 1,082,717
Leasehold improvements	1,931,762	1,943,534
Equipment used in manufacturing	2,432,242	2,166,743
Equipment used in research & development	2,343,930	2,506,644
Equipment used in the field	216,218	208,005
Software	480,740	420,301
Property and equipment	8,277,769	8,327,944
Less: accumulated depreciation and amortization	(7,158,883)	(7,100,542)
	$ 1,118,886	$ 1,227,402

Depreciation and leasehold improvement amortization expense was $0.7 million and $1.3 million for the years ended December 31, 2021 and 2020, respectively.

Note 7. Accrued Liabilities

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

	December 31,	
	2021	2020
Accrued employee bonuses	$ 1,254,355	$ 436,799
Payroll and employee benefit accruals	389,385	694,058
Accrued product warranty	97,512	92,696
Other accrued liabilities	281,317	236,325
	$ 2,022,569	$ 1,459,878

Note 8. Debt Obligations.

Current portion of long-term debt consisted of the following as of the dates indicated:

	December 31,	
	2021	2020
SVB Term Loan	$ 5,000,000	$ 2,000,000
PPP Loan	—	857,040
2021 Insurance Note	167,586	—
2020 Insurance Note	—	165,099
	$ 5,167,586	$ 3,022,139

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

	December 31,	
	2021	2020
SVB Term Loan, net of discount and debt issuance costs	$ 5,178,629	$ 7,708,348
PPP Loan	—	859,960
	$ 5,178,629	$ 8,568,308

SVB Term Loan

On June 24, 2020 (the "Closing Date"), the Company entered into the Loan Agreement with SVB.

The proceeds from the SVB Term Loan in the amount of $10.0 million were fully funded on June 25, 2020. Together with cash on hand, the proceeds were used to repay in full all outstanding amounts and fees due under the MidCap Credit Facility in an aggregate amount equal to $7.5 million, including collateral agent legal fees and prepayment fees, in addition to the Company's subordinated convertible promissory note to QNAH (the "QNAH Convertible Note") and related accrued interest in the aggregate amount of $3.2 million. 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 in other income (expense) in the accompanying 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 as a result of this extinguishment.

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 originally required interest-only payments through June 30, 2021. As a result of the Company's achievement of an equity milestone defined in the Loan Agreement during the quarter ended June 30, 2021, the interest-only period was extended for six months through December 31, 2021. Following the extended interest-only period, the Company is obligated to make 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, are subject to early termination fees in an amount equal to 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), and the Company's future subsidiaries, if any, may be required to become co-borrowers or guarantors under the Loan Agreement. In addition, the Company must comply with a financial covenant in the SVB Term Loan requiring the Company to maintain unrestricted cash, including short term available-for-sale securities, 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.

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 approximately $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 as equity.

The Company included $0.6 million and $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 of current portion, discount and debt issuance costs in the accompanying consolidated balance sheets as of December 31, 2021 and 2020, respectively. Amortization of the debt discount associated with the SVB Term Loan was $0.5 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively, and was included in interest expense in the consolidated statements of operations. The effective interest rate for the year ended December 31, 2021 was 10.47%.

The remaining principal repayments due under the SVB Term Loan as of December 31, 2021 are as follows for each fiscal year:

2022	$	5,000,000
2023		5,000,000
Total SVB Term Loan payments		10,000,000
Less discount and deferred financing costs		(621,371)
Plus final fee premium		800,000
Total SVB Term Loan, net	$	10,178,629

Paycheck Protection Program Loan

On April 21, 2020, the Company received proceeds from a PPP Loan in the amount of $1.7 million from SVB, as lender. The PPP Loan was evidenced by a promissory note which bore interest at an annual rate of 1%, and contained customary events of default relating to, among other things, payment defaults and breaches of representations, warranties or terms of the PPP Loan documents. Under the CARES Act and PPP Flexibility Act, loan forgiveness was available for the sum of documented payroll costs (including benefits), rent and utility obligations, and interest on certain of the Company's other debt obligations incurred during the 24-week period beginning on the date of loan approval, as defined by the applicable guidelines and the SBA. The Company applied for full PPP Loan forgiveness in October 2020.

On May 26, 2021, the Company received notification from SVB that the PPP Loan and related accrued interest was forgiven in full by the SBA, and the PPP Loan note had been cancelled. Accordingly, the Company recorded a gain on forgiveness of the PPP Loan of $1.7 million for the year ended December 31, 2021, included in other income (expense) in the accompanying consolidated statements of operations. The PPP Loan is subject to SBA review at any time before or after the SBA remits payment to the lender. The Company has not accrued any liability associated with risk of an adverse SBA review.

Insurance Note

On April 27, 2020, the Company entered into a commercial financing agreement to extend the payment period related to its director and officer insurance policy (the "2020 Insurance Note"). The 2020 Insurance Note required a down payment to be made upon signing the agreement equal to approximately $0.2 million. The unpaid premium balance of approximately $0.7 million was financed at an annual rate of 3.61% and was repaid in nine equal monthly payments of principal and interest through February 2021.

On May 5, 2021, the Company entered into a new commercial financing agreement to extend the payment period related to its director and officer insurance policy (the "2021 Insurance Note"). The 2021 Insurance Note required a down payment to be made upon signing the agreement equal to approximately $0.4 million. The remaining unpaid premium balance of approximately $0.7 million has been financed at an annual rate of 3.57% and is to be repaid in nine equal monthly payments of principal and interest beginning in June 2021. The 2021 Insurance Note contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties or terms of the 2021 Insurance Note documents, and 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, 2021 and 2020 as follows:

	Years Ended December 31,	
	2021	2020
Product revenue:		
Instrument	$ 1,385,665	$ 869,035
Consumables	3,786,923	3,030,612
Total product revenue	5,172,588	3,899,647
Product-related services revenue:		
Custom RUO assay design	48,350	1,393,316
RUO sample processing	3,685,890	2,597,891
Total product-related services revenue	3,734,240	3,991,207
Total product and product-related services revenue	$ 8,906,828	$ 7,890,854

As 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 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. 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.

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 years ended December 31, 2021 and 2020.

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. For the year ended December 31, 2020, collaborative development services revenue was generated through statements of work entered into under a Master Assay Development, Commercialization and Manufacturing Agreement (the "Governing Agreement") with QIAGEN Manchester Limited ("QML") discussed below.

	Years Ended December 31,	
	2021	2020
Collaborative development services	$ —	$ 658,010

Master Assay Development, Commercialization and Manufacturing 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. Remaining agreed upon procedures associated with these statements of work were completed in the prior year and no additional collaborative development services programs have been entered into as of December 31, 2021.

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.

Contract Liabilities

The Company may receive 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 $0.1 million were included in contract liabilities – current and an additional immaterial amount of contract liabilities were included in other non-current liabilities in the consolidated balance sheets as of December 31, 2021, reflecting the period in which the Company expects to realize the deferred revenue.

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, 2021	$ 103,580	$ -	$ 93,884	$ 197,464
Deferral of revenue	286,349	-	587,091	873,440
Recognition of deferred revenue	(261,400)	-	(650,354)	(911,754)
Balance at December 31, 2021	$ 128,529	$ —	$ 30,621	$ 159,150

	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

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 $0.1 million and $0.2 million during the years ended December 31, 2021 and 2020, 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 2022 include $72,624 of revenue-based payments payable as of December 31, 2021 and an estimate of additional revenue-based payments to be made throughout the remainder of 2022 relating to revenue generated in the first, second and third quarters of 2022 using actual revenue generated in the same quarters in 2021. 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:

2022	$	548,301
2023		400,000
2024		400,000
2025		400,000
2026		400,000
2027 and beyond		2,233,792
Total NuvoGen obligation payments		4,382,093
Plus interest accretion		67,088
Total NuvoGen obligation, net	$	4,449,181

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 $(67,088) and $(79,376) as of December 31, 2021 and 2020, respectively. Discount accreted during the years ended December 31, 2021 and 2020 was $(12,288), and $(12,935), respectively, and was included in interest expense in the consolidated statements of operations.

Note 11. Leases

Operating Leases

The Company leases office space under agreements classified as operating leases. The Company's active leases as of December 31, 2021 relate to the Company's office and manufacturing space in Tucson, Arizona, and expire in 2025. The Company's leases do not include any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees.

The Company amended its Tucson facility leases in December 2020 to extend the terms of the leases for one year, through January 31, 2022 and again in September 2021 to extend the terms of the leases for three years, through January 31, 2025. The lease extensions were treated as lease modifications for accounting purposes, and allow for an additional extension of two years on the same terms and conditions of the existing amended lease agreement, 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 options, but in no event less than the last applicable rental rate. The Company has not accounted for these renewal options in the calculation of the lease liabilities and right-of-use assets as the Company is not reasonably certain to exercise the options.

In the first quarter of 2021, the Company closed its development laboratory in San Carlos, California and, as a result, $0.2 million of operating right-of-use assets related to the abandonment of the laboratory were written off to research and development expense for the year ended December 31, 2021.

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,	
	2021	2020
Operating leases		
Operating lease cost	$ 503,130	$ 752,413
Variable lease cost	88,708	125,792
Total rent expense	$ 591,838	$ 878,205

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

	Years Ended December 31,	
	2021	2020
Cash paid for amounts included in measurement of operating lease liabilities	$ 514,453	$ 883,252
Establishment of operating lease liabilities arising from obtaining right-of-use assets	$ 1,302,457	$ 447,987
Weighted-average remaining lease term – operating leases	3.1	1.7
Weighted-average discount rate – operating leases	5.8%	8.0%

As of December 31, 2021, remaining maturities of the Company's operating leases are as follows:

2022	$ 481,548
2023	484,719
2024	484,631
2025	40,382
Total	1,491,280
Less present value discount	(127,954)
Total operating lease liabilities	1,363,326
Less operating lease liabilities – current	(413,865)
Operating lease liabilities - non-current	$ 949,461

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,	
	2021	2020
Financing leases		
Amortization of right-of-use assets	$ 23,118	$ 42,826
Interest on lease liability	5,793	8,938
Total financing lease cost	$ 28,911	$ 51,764

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

	Years Ended December 31,	
	2021	2020
Weighted-average remaining lease term – financing leases	2.8	3.4
Weighted-average discount rate – financing leases	9.77%	9.77%

As of December 31, 2021, remaining maturities of the Company's financing leases are as follows:

2022	$ 20,716
2023	18,396
2024	16,080
Total	55,192
Less present value discount	(7,081)
Financing lease liabilities, net	$ 48,111

Financing lease liabilities net of discount of $48,111, of which $16,807 and $31,304 were included in other current liabilities and other non-current liabilities, respectively, and financing right-of-use assets of $43,651, were included in property and equipment, net, in the consolidated balance sheet as of December 31, 2021.

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 common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table provides 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,	
	2021	2020
Numerator:		
Net loss	$ (17,145,170)	$ (20,870,218)
Denominator:		
Weighted-average shares outstanding-basic and diluted *	6,936,131	4,627,918
Net loss per share, basic and diluted	$ (2.47)	$ (4.51)

*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,	
	2021	2020
Options to purchase common stock	559,336	487,227
Series A Preferred	158,545	158,545
Common stock warrants	58,688	58,688
Unvested restricted stock units	31,177	12,214

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. In March 2020, 211,784 of the pre-funded warrants were exercised for proceeds of $31,768. In June 2021, the remaining 148,995 pre-funded warrants were exercised on a cashless, net exercise basis, resulting in the issuance of 144,881 shares of common stock.

In connection with the SVB Term Loan (see Note 8), 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 following table shows the common stock warrants outstanding as of December 31, 2021:

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
June 2020	42,894	11.6565	2030

Note 14. Stockholders' Equity

Reverse Stock Split

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.

Equity Offerings

Securities Purchase Agreement

In September 2019, concurrently with the closing of an 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. For further discussion of pre-funded warrant activity see Note 13.

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 was able to offer and sell, from time to time, through Cantor, shares of its common stock, par value $0.001 per share, 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 Company paid Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of shares for all sales made under this agreement. The shares were offered and sold pursuant to the Company's prior shelf registration statement on Form S-3 (File No. 333-229045).

During the year ended December 31, 2021, the Company sold 2,050,879 shares of common stock under the ATM Offering at then-market prices for total gross proceeds of approximately $11.0 million. After paying sales commissions owed in connection with the ATM Offering of approximately $0.3 million, the Company's aggregate net proceeds for the year ended December 31, 2021 were approximately $10.7 million.

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 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.

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, 2021.

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. The Company did not receive cash proceeds from the issuance of such shares. The value of this commitment consideration, as well as related transaction costs of approximately $0.1 million was included in selling, general and administrative expense in the accompanying consolidated statements of operations during the year ended December 31, 2020.

During the year ended December 31, 2021, the Company sold 154,372 shares of common stock under the LP Purchase Agreement at a weighted average price of $5.83 per share for total gross proceeds of $0.9 million compared to 197,632 shares of common stock at a weighted average price of $4.94 per share for total gross proceeds of $1.0 million during the year ended December 31, 2020.

Pursuant to the March 2022 Purchase Agreement (see Note 17), the Company may not sell any shares of its common stock under the LP Purchase Agreement for the remainder of the 36-month term of the LP Purchase Agreement.

Common Stock

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").

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 558,865 shares of the Company's common stock available for issuance under the 2020 Plan as of December 31, 2021 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.

In July 2021, the Company's Board of Directors adopted the Company's 2021 Inducement Plan (the "2021 Inducement Plan"), pursuant to which 300,000 shares were initially authorized and reserved for issuance 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"). There were 160,000 shares of the Company's stock available for issuance under the 2021 Inducement Plan as of December 31, 2021, in addition to shares that may become available from time to time as shares of the Company's common stock subject to outstanding awards granted under the 2021 Inducement Plan 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 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,	
	2021	2020
Selling, general and administrative	$ 1,154,000	$ 1,461,190
Research and development	141,281	106,267
Cost of product and product-related services revenue	22,074	17,328
	$ 1,317,355	$ 1,584,785

The following table summarizes stock option activity during the two-year period ended December 31, 2021:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at January 1, 2020	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
Granted	153,833	5.45		
Exercised	(75)	4.35		$ 107
Forfeited	(52,874)	11.98		
Expired/Cancelled	(28,775)	20.39		
Balance at December 31, 2021	559,336	$ 13.93	8.2	$ 30,267
Exercisable at December 31, 2020	187,031	$ 27.07	7.5	$ 305
Exercisable at December 31, 2021	298,987	$ 20.14	7.4	$ 6,269

The weighted-average fair value of stock options granted was $4.38 and $6.40 for the years ended December 31, 2021 and 2020, respectively. The 2020 stock option activity includes no Inducement Awards granted during the year ended December 31, 2020 compared with 110,000 Inducement Awards granted during the year ended December 31, 2021. As of December 31, 2021, total unrecognized compensation cost related to non-vested stock options was approximately $1.3 million, which is expected to be recognized over approximately 2.52 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:

	2021	2020
Fair value of common stock on grant date	$4.07 - 6.25	$4.35 - 11.25
Risk-free interest rate	0.85% - 1.20%	0.34% - 1.65%
Expected volatility	104.2% - 107.3%	109.1% - 149.9%
Expected term	5.2 to 6.1 years	5.4 to 5.9 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 during the years ended December 31, 2021 and 2020.
- *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 activity during the two-year period ended December 31, 2021:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at January 1, 2020	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
Granted	30,000	5.20
Released	(4,529)	29.13
Forfeited	(6,508)	24.18
Balance at December 31, 2021	31,177	$ 6.93
Vested and unissued at December 31, 2021	4,148	$ 9.60

The weighted-average fair value of RSUs granted was $5.20 and $7.83 for the years ended December 31, 2021 and 2020, respectively. The 2020 RSU award activity includes no Inducement Awards granted during the year ended December 31, 2020 compared with 30,000 Inducement Awards granted during the year ended December 31, 2021. As of December 31, 2021, total unrecognized compensation cost related to non-vested RSUs was approximately $0.2 million, which is expected to be recognized over approximately 1.47 years.

Vested and unissued awards at December 31, 2021 represents RSU awards granted in August 2018 and November 2021 for which a portion of the awards vested on December 31, 2021, but for which issuance of shares occurred in January 2022.

2014 Employee Stock Purchase Plan

In April 2015, the Company's stockholders approved the 2014 Employee Stock Purchase Plan (the "2014 ESPP), which became effective in May 2015. Under the 2014 ESPP, the number of shares of common stock reserved for issuance automatically increased on January 1 of each calendar year, from January 1, 2016 to January 1, 2021 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 2014 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 2014 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.

In August 2021, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Amended and Restated 2014 Employee Stock Purchase Plan (the "Amended 2014 ESPP"). Upon approval of the Amended 2014 ESPP, 500,000 shares of the Company's common stock were reserved for issuance under the Amended 2014 ESPP in addition to 24,285 shares of the Company's common stock reserved for issuance under the original 2014 ESPP. The Amended 2014 ESPP does not contain an evergreen provision all other provisions of the 2014 ESPP remained unchanged.

Amounts recognized in the consolidated statements of operations with respect to the Amended 2014 ESPP were as follows:

	Years Ended December 31,	
	2021	2020
Selling, general and administrative	$ 34,219	$ 12,106
Research and development	11,643	5,248
Cost of product and product-related services revenue	11,807	3,832
	$ 57,669	$ 21,186

During the year ended December 31, 2021, employees purchased the following shares at the end of each of the six-month purchase periods:

	June 2021		December 2021	
	Number of Shares	Price per Share	Number of Shares	Price per Share
Total number of shares purchased	13,637	$ 3.92	20,326	$ 3.56

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 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	

As of December 31, 2021, approximately 503,959 shares of the Company's common stock were reserved for future issuance under the Amended 2014 ESPP.

The Company recognizes employee stock purchase plan expense based on the fair value of 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 employee stock purchase plan stock purchase rights for the periods presented were as follows:

	2021	2020
Fair value of common stock	$4.67 - 5.85	$8.70 - 9.75
Risk-free interest rate	0.04% - 0.08%	0.18% - 1.58%
Expected volatility	71.9% - 89.2%	65.8% - 88.9%
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 years ended December 31, 2021 and 2020.
- *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 Amended 2014 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 years ended December 31, 2021 and 2020. As of December 31, 2021, 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. Product warranty liabilities of approximately $97,000 and $23,000 were included in accrued liabilities and other non-current liabilities, respectively, in the accompanying consolidated balance sheets as of December 31, 2021. Expense relating to the recording of this reserve is recorded in cost of product and product-related services revenue within the accompanying consolidated statements of operations.

	Years Ended December 31,	
	2021	2020
Beginning balance	$ 92,696	$ 94,482
Cost of warranty claims	(166,641)	(32,866)
Increase in warranty reserve	194,330	31,080
Ending balance	$ 120,385	$ 92,696

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, 2021 and 2020.

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 $3.2 million and $3.0 million of uncertain tax positions as of December 31, 2021 and 2020, 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, 2021 or 2020, and has not recognized interest or penalties during the years ended December 31, 2021 and 2020, 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,	
	2021	2020
U.S. pre-tax loss	$ (17,156,070)	$ (20,855,184)
Foreign pre-tax gain (loss)	33,375	(619)
Loss before income taxes	$ (17,122,695)	$ (20,855,803)

The components of income tax expense are as follows:

	Years Ended December 31,	
	2021	2020
Current:		
Federal	$ —	$ —
State	13,769	10,860
Foreign	8,706	3,555
Total current income tax expense	$ 22,475	$ 14,415
Deferred:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total deferred income tax expense	$ —	$ —
Total income tax expense	$ 22,475	$ 14,415

The Company's actual income tax expense for the years ended December 31, 2021 and 2020 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,	
	2021	2020
Computed tax (benefit) at 21%	$ (3,586,925)	$ (4,379,719)
State taxes, net of federal benefit	(1,177,951)	(832,055)
Stock-based compensation	240,177	310,811
Foreign tax rate differential	(2,171)	3,685
Return to provision	53,340	26,120
Nontaxable loan forgiveness	(360,570)	—
Other	9,048	31,850
Research and development tax credit - state	(265,362)	(218,991)
Research and development tax credit - federal	(212,408)	(197,836)
Uncertain tax position adjustment for prior periods	(6,395)	(5,694)
Increase in valuation allowance	5,331,692	5,276,244
	$ 22,475	$ 14,415

Deferred tax assets and liabilities comprise the following:

	Years Ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 47,752,053	$ 43,308,483
Research and development credits	3,940,199	3,475,341
Deferred revenue	42,802	50,429
Inventory reserve	6,806	6,653
Fixed assets and intangibles	304,019	313,117
Accrued NuvoGen liability	1,196,563	1,274,896
Lease liability	366,653	269,147
Other	711,343	211,574
Gross deferred tax assets	54,320,438	48,909,640
Valuation allowance	(53,958,617)	(48,626,925)
Deferred tax assets, net	361,821	282,715
Deferred tax liabilities:		
Right of use asset	361,821	257,705
Other	—	25,010
Total deferred tax liabilities	361,821	282,715
Net deferred tax assets (liabilities)	$ -	$ -

As of December 31, 2021, the Company has estimated federal and state net operating loss ("NOL") carryforwards of approximately $194.0 million and $125.6 million for federal and state income tax purposes, respectively. $121.8 million of the federal NOLs are scheduled to expire from 2023 through 2037, while the remaining NOLs do not expire. $124.6 million of the state NOLs are scheduled to expire from 2024 through 2041, while the remaining NOLs do not expire. The Company's federal and state tax credit carryforwards begin expiring in 2022.

For financial reporting purposes, valuation allowances of $54.0 million and $48.6 million at December 31, 2021 and 2020, 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, 2021 was primarily due to increased operating losses. The Company has established a valuation allowance against its entire net deferred 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,	
	2021	2020
Balance at beginning of year	$ 2,960,842	$ 2,731,015
Increases to prior positions	—	—
Decreases to prior positions	(6,395)	(5,694)
Increases for current year positions	238,884	235,521
Balance at end of year	$ 3,193,331	$ 2,960,842

As of December 31, 2021, the Company had $3.2 million of gross unrecognized tax benefits, related to research and experimental tax credits. The Company had no unrecognized tax benefits as of December 31, 2021, 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 contained 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 permitted NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021, and allowed 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 did not experience 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, 2021, the earliest year subject to examination is 2018 for U.S. federal tax purposes. The earliest year subject to examination is 2017 for the state jurisdictions, and 2019 for France. However, the Company's federal and state NOLs and tax credit carryforwards for periods ending December 31, 2002 and thereafter remain subject to examination by the United States and certain states.

Note 17. Subsequent Events

On March 21, 2022, pursuant to a Securities Purchase Agreement (the "March 2022 Purchase Agreement") with a single investor the Company issued and sold to the investor 3,244,987 units at a price of $2.312 per unit (less $0.001 for each pre-funded warrant purchased in lieu of a share of common stock) for gross proceeds to the Company, before deducting the placement agent fees and other estimated fees and expenses, of approximately $7.5 million. Each unit consisted of one share of common stock (or one pre-funded warrant in lieu thereof), a common warrant to purchase one share of the Company's common stock with a term of 24 months from the issuance date, and a common warrant to purchase one share of the Company's common stock with a term of 66 months from the issuance date. Each of the common warrants is exercisable six months following the closing date, and has an exercise price of $2.062 per share. Each pre-funded warrant has an exercise price of $0.001 per share and does not expire until exercised in full.

The securities sold under the March 2022 Purchase Agreement have not been registered under the Securities Act or any state securities laws. The Company has agreed to file a resale registration statement with the SEC for purposes of registering the resale of the shares of common stock issued and issuable pursuant to the March 2022 Purchase Agreement within 10 days following the filing of this Annual Report on Form 10-K.

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, 2021, 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, 2021, 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, 2021.

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, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

Not applicable.

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	58	President, Chief Executive Officer and Director
Shaun D. McMeans	60	Senior Vice President, Chief Financial Officer, Treasurer and Secretary
Byron T. Lawson	47	Senior Vice President, Chief Commercial Officer
Non-Employee Directors		
Ann F. Hanham, Ph.D. (3)	69	Chair of Board of Directors
Harry A. George (1)	73	Director
Michelle R. Griffin (1)(2)	56	Director
Donnie M. Hardison (2)	71	Director
Christopher P. Kiritsy (1)(4)	57	Director
James T. LaFrance (1)(3)	63	Director
Lee R. McCracken (2)(3)	64	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and governance committee.

(4) Appointed to the Board of Directors in January 2022.

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 before that 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 the 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 in a variety of divisional, sector and corporate leadership roles at Corning, Incorporated, a multinational technology company that specializes in specialty glass, ceramics and related materials and technologies including advanced optics, primarily for industrial and scientific applications. Mr. Lubniewski earned a Bachelor of Science degree 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 Bachelor of Science degree in Accounting from The Pennsylvania State University.

Byron T. Lawson. Mr. Lawson has served as our Senior Vice President and Chief Commercial Officer since January 2020 and previously served as our Senior Vice President, Pharma Business Unit since January 2018. Prior to this, he served as our Vice President, Commercial Operations since April 2016 and 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 increasing 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 has served as chair of our Board of Directors since January 2021. Prior to this, Dr. Hanham served as Lead Independent Director from April 2019 to December 2020 and as chair of our Board of Directors from March 2017 to March 2019. Since March 2017, Dr. Hanham has provided independent management consulting as a sole proprietor. Previously, she was the founding and managing partner of BAR Capital LLC, an investment company, a position she has held from December 2013 to March 2017. From February 2000 to November 2013, Dr. Hanham was the Managing Director and General Partner of Burrill and Company, a life science investment company. Prior to that, Dr. Hanham held positions of increasing responsibility in product development, medical affairs, and clinical and regulatory affairs at various companies, including InterMune Inc., Otsuka America Pharmaceuticals, Inc. (“Otsuka”), Celtrix Pharmaceuticals, Inc. (“Celtrix”), and Becton Dickinson and Company (“BD”). InterMune, Inc., Otsuka and Celtrix are, or prior to respective acquisitions, were clinical-stage biopharmaceutical companies, and BD is a life sciences discovery and diagnostics company. Dr. Hanham also currently serves on the board of directors of SCYNEXIS (Nasdaq: SCYX). Dr. Hanham received her Bachelor of Science 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.

Harry A. George. Mr. George has served on our board of directors since 2002 and served as the chair of our board of directors from December 2007 until September 2013. Mr. George co-founded Solstice Capital, a venture capital firm, in 1995 and serves as its Managing General Partner. Mr. George served as President and CFO of Radiance Therapeutics from June 2018 to September 2020. He has also served as a member of the board of directors of a number of other 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 his Bachelor of Arts degree 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. 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.

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. 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. (Nasdaq: TRBN) 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. (Nasdaq: DNRN) 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 Bachelor of Science degree 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.

Donnie M. Hardison. Mr. Hardison has served on our Board of Directors since May 2016. Since February 2021, he has been working as an independent healthcare consultant. He was most recently the President and Chief Executive Officer, and served on the board of directors, of Biotheranostics, Inc., a molecular diagnostic company focused on oncology, from February 2017 until it was acquired by Hologic, Inc. in February 2021. From April 2010 to March 2016, Mr. Hardison was the President and Chief Executive Officer of Good Start Genetics, a molecular genetic testing and information company. For more than 20 years prior to that, Mr. Hardison held various 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 or advisor of several private companies, including Stemina Biomarker Discovery, Inc., Seventh Sense Biosystems, BioPorto, Inc. 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.

Christopher P. Kiritsy. Mr. Kiritsy has served on our Board of Directors since January 2022. Mr. Kiritsy currently serves as audit and compensation committee chairs and on the board of directors of Pieris Pharmaceuticals, Inc. (Nasdaq: PIRS). Since 2018, Mr. Kiritsy has been the managing member of Precision Kapital, LLC, a private investment and advisory firm that he founded. Prior to forming Precision Kapital, Mr. Kiritsy co-founded Arisaph Pharmaceuticals, Inc. ("Arisaph") and served as Arisaph's President and Chief Executive Officer until its exit in 2018. At Arisaph, Mr. Kiritsy evolved the drug discovery organization from an academic orientation to a clinical development enterprise, taking several cardiometabolic products into clinical development. Prior to Arisaph, Mr. Kiritsy served as Executive Vice President, Corporate Development and Chief Financial Officer of Kos Pharmaceuticals, Inc. (Nasdaq: KOSP). Mr. Kiritsy is a seasoned entrepreneur, who possesses more than 25 years of business and technical experience in the biopharmaceutical industry. He received his Bachelor of Arts degree in Biology from Bowdoin College and an MBA from Boston University. Our Board of Directors believes that Mr. Kiritsy'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.

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 working since January 2015 as a sales, marketing, strategy development and commercial operational management consultant for LaFrance Consulting LLC, a firm he founded. He current serves on two additional boards, Aspira Women's health (Nasdaq: AWH); formerly Vermillion, Inc. (Nasdaq: VRMC) as chairman, and as an independent director of privately held Personal Genome Diagnostics in Baltimore, Maryland. He served as interim Chief Executive Officer of Vermillion, Inc. in 2014 and as Chief Executive Officer of Omnyx, LLC for GE Healthcare from 2012 to 2013. Mr. LaFrance held a series of Senior Management roles at Ventana Medical Systems (now Roche Tissue Diagnostics), or Ventana, including general management of the North American and international commercial operations. Prior to working for Ventana, Mr. LaFrance served in leadership roles in strategic marketing and business development at Bayer Diagnostics. He earned a Bachelor of Arts degree in Economics from the University of Connecticut and holds an MBA 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. Since May 2021, Mr. McCracken currently serves as Entrepreneur in Residence at Thorne HealthTech, a leader in the development of innovative solutions for personalized approaches to health and wellbeing, and Chair of the Drawbridge Health, Inc. board of directors, a company focused on enabling personal diagnostic testing. From June 2017 to April 2021, Mr. McCracken was the Chief Executive Officer of Drawbridge Health, Inc. From May 2016 to May 2017 and from April 2013 to March 2014, Mr. McCracken was a strategic and restructuring consultant in the regenerative medicine and diagnostics industries through his firm, McCracken Consulting. In addition, he served as Chief Executive Officer of Gensignia Life Sciences, Inc., a molecular diagnostics company, from April 2014 through May 2016.

Mr. McCracken previously held 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 MBA 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 Bachelor of Science degree 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 regarding each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

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

- Class I, which consists of Mr. McCracken and Mr. LaFrance, whose terms will expire at our annual meeting of stockholders to be held in 2022.
- Class II, 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; and
- Class III, which consists of Dr. Hanham and Ms. Griffin, whose terms will expire at our annual meeting of stockholders to be held in 2024.

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, Mr. LaFrance and Mr. Kiritsy. 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 and cybersecurity-related 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 and cybersecurity 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 2021, 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 2021 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, 2021, which consist of our principal executive officer and our two other most highly compensated executive officers as of December 31, 2021, 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	2021	460,000	—	276,000	741	736,741
President and Chief Executive Officer	2020	416,000	930,747	93,600	741	1,441,088
Shaun D. McMeans	2021	370,000	—	139,860	741	510,601
Senior Vice President and Chief Financial Officer	2020	358,000	396,744	48,330	741	803,815
Byron T. Lawson	2021	333,000	—	106,560	741	440,301
Chief Commercial Officer	2020	303,000	182,093	45,450	741	531,284

(1) We did not grant option awards to our named executive officers in 2021. 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 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 2021 and 2020.

(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. In January 2022, the base salaries for Mr. Lubniewski, Mr. McMeans and Mr. Lawson were increased to $538,000, $385,000 and $345,000, 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 by our Board of Directors, based on the recommendation of our Compensation Committee and 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 2021, 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 2021, 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 2021, 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 2021 were based upon financial and strategic goals. Specific goals included direct revenue growth, customer metrics and objectives related to product development. The financial and strategic goals were weighted at 20% and 80%, respectively, 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 2021.

In January 2022, our Board of Directors determined that the 2021 corporate goals related to direct revenue growth, customer metrics and product development had been achieved at an aggregate level of 80%, to be allocated based on individual performance objectives. As a result, our Board of Directors awarded bonuses of $276,000, $139,860 and $106,560 to Mr. Lubniewski, Mr. McMeans and Mr. Lawson, respectively, representing the performance-adjusted percentage of each executive's target bonus 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, 2021, our named executive officers have been granted both stock option awards and RSUs.

Prior to the initial public offering, we granted all equity awards pursuant to the 2011 Plan and the 2001 Plan. All equity awards granted since our initial public offering have been granted pursuant to the 2014 Plan, the 2020 Plan and the 2021 Inducement 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 $460,000 (which has been increased, most recently in January 2022 to $538,000), an annual target performance bonus of up to 75% of his 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 $370,000 (which has been increased, most recently in January 2022 to $385,000), an annual target performance bonus of up to 40% of his base salary (increased in January 2022 to 55% 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 $333,000 (which has been increased, most recently in January 2022 to $345,000), an annual target performance bonus of up to 50% of his 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, 2021.

			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		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	5,838	828	51.00	8/16/2028	—	—
	(2)	5/23/2019	17,919	2,081	33.30	5/23/2029	—	—
		8/15/2019	7,500	—	14.25	8/15/2029	—	—
		1/23/2020	35,833	—	9.90	1/23/2030	—	—
	(1)	8/20/2020	28,354	51,646	7.20	8/20/2030	—	—
	(4)	8/16/2018	—	—			413	21,063
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	5,838	828	51.00	8/16/2028	—	—
		8/15/2019	3,166	—	14.25	8/15/2029	—	—
		1/23/2020	15,833	—	9.90	1/23/2030	—	—
	(1)	8/20/2020	11,819	21,514	7.20	8/20/2030	—	—
	(4)	8/16/2018	—	—			203	10,353
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		
		5/31/2017	333	—	51.90	5/31/2027		
		7/25/2017	500	—	35.85	7/25/2027		
	(1)	8/16/2018	1,750	250	51.00	8/16/2028		
		8/6/2019	4,333	—	20.70	8/6/2029		
		9/12/2019	2,333	—	12.00	9/12/2029		
		1/7/2020	4,666	—	11.25	1/7/2030		
	(3)	8/20/2020	6,406	11,594	7.20	8/20/2030		
	(4)	8/16/2018	—	—			163	8,313

(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

2021 Inducement Plan

In July 2021, the Company's Board of Directors adopted the Company's 2021 Inducement Plan (the "2021 Inducement Plan"), pursuant to which 300,000 shares were initially authorized and reserved for issuance 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"). There were 160,000 shares of the Company's stock available for issuance under the 2021 Inducement Plan as of December 31, 2021, in addition to shares that may become available from time to time as shares of the Company's common stock subject to outstanding awards granted under the 2021 Inducement Plan 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.

Stock Awards. The 2021 Inducement Plan provides for the grant of 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 2021 Inducement Plan will not exceed 300,000 shares.

If any shares of our common stock issued pursuant to an award granted under the 2021 Inducement 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 2021 Inducement Plan.

The following shares of our common stock will not become available again for issuance under the 2021 Inducement Plan: (i) any shares repurchased by us on the open market with the proceeds of the exercise or strike price of an award granted under the 2021 Inducement Plan or a Prior Plan Award; and (ii) in the event that a stock appreciation right granted under the 2021 Inducement 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. Awards may only be granted to persons who are Eligible Employees described in Section 1(a) of the Plan, where the Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Marketplace Rules or is otherwise permitted pursuant to Rule 5635(c) of the Nasdaq Marketplace Rules.

Administration. The 2021 Inducement Plan will be administered by our Board of Directors, which may in turn delegate some or all of the administration of the 2021 Inducement 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 2021 Inducement 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.

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, 2021, option awards covering an aggregate of 252,275 shares of our common stock 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, 2021, option awards covering an aggregate of 182,095 shares of our common stock, and an additional 1,177 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, 2021, option awards under the 2011 Plan covering an aggregate of 14,966 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 2014 ESPP in December 2014 and our stockholders approved the 2014 ESPP in April 2015. The 2014 ESPP became effective on May 5, 2015 in connection with our initial public offering. The purpose of our employee stock purchase plans 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 employee stock purchase plans are intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Our Board of Directors has delegated its authority to administer the ESPP to our compensation committee.

The 2014 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).

In August 2021, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Amended and Restated 2014 Employee Stock Purchase Plan (the "Amended 2014 ESPP"). Upon approval of the Amended 2014 ESPP, 500,000 shares of the Company's common stock were reserved for issuance under the Amended 2014 ESPP in addition to 24,285 shares of the Company's common stock reserved for issuance under the original 2014 Employee Stock Purchase Plan. The Amended 2014 ESPP does not contain an evergreen provision.

Offerings and Purchases. The Amended 2014 ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the Amended 2014 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 Amended 2014 ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the Amended 2014 ESPP. Unless otherwise determined by our Board of Directors, common stock will be purchased for accounts of employees participating in the Amended 2014 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 Amended 2014 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 Amended 2014 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 Amended 2014 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 Amended 2014 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. We made no matching contributions into the 401(k) plan for either of the year ended December 31, 2021. 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, 2021 to each of our non-employee directors:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Ann F. Hanham	75,000	25,000	100,000
Michelle R. Griffin	56,000	25,000	81,000
Harry A. George	42,500	25,000	67,500
Donnie M. Hardison	47,000	25,000	72,000
James T. LaFrance	47,500	25,000	72,500
Lee R. McCracken	46,000	25,000	71,000
Timothy B. Johnson (2)	4,677	—	4,677

(1) As of December 31, 2021, the aggregate number of outstanding options to purchase our common stock held by our non-employee directors were: Dr. Hanham: 10,398, Ms. Griffin: 9,999, Mr. George: 10,532; Mr. Hardison: 10,798; Mr. LaFrance: 10,798, Mr. McCracken: 10,798 and Mr. Johnson 21,737. The dollar amounts in this column represent the aggregate grant date fair value of stock option awards granted in 2021. 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.

(2) Mr. Johnson served as our Executive Chairman until his resignation in January 2021.

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, 2021:

- 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, 2021.

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:			
2011 Equity Incentive Plan	14,966	49.94	—
2014 Equity Incentive Plan (1) (2)	183,272	26.12	—
Amended 2014 Employee Stock Purchase Plan (3)	—	N/A	479,674
2020 Equity Incentive Plan	252,275	6.87	558,865
Equity compensation plans not approved by security holders (4)	140,000	5.29	160,000
Total	590,513		1,038,539

(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. Upon adoption of the 2020 Plan in August 2020, there were no additional annual authorized share increases.

(2) The number of shares to be issued upon exercise of outstanding options, RSUs, warrants and rights under the 2014 Equity Incentive Plan includes 1,177 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, 2020, the number of shares authorized for issuance under our 2014 Employee Stock Purchase Plan was 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). In August 2021, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Amended 2014 ESPP. Upon approval of the Amended 2014 ESPP, 500,000 shares of the Company's common stock were reserved for issuance under the Amended 2014 ESPP in addition to 24,285 shares of the Company's common stock reserved for issuance under the original 2014 Employee Stock Purchase Plan. The Amended 2014 ESPP does not contain an evergreen provision.

(4) In July 2021, the Company's Board of Directors adopted the Company's 2021 Inducement Plan (the "2021 Inducement Plan"), pursuant to which 300,000 shares were initially authorized and reserved for issuance 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"). There were 160,000 shares of the Company's stock available for issuance under the 2021 Inducement Plan as of December 31, 2021.

Principal Stockholders

The following table sets forth certain information regarding the ownership of the Company's common stock as of February 28, 2022 by: (i) each director; (ii) each of our executive officers named in the Summary Compensation Table above; (iii) all executive officers and directors of the Company as a group; and (iv) all those known by the Company to be beneficial owners of more than five percent of its common stock.

The table is based upon information supplied by officers, directors and principal stockholders, Schedules 13G filed with the SEC and other sources believed to be reliable by us. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 7,590,733 shares outstanding on February 28, 2022, 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		
Samjo Capital, LLC, Samjo Management, LLC and Andrew N. Wiener (1)	615,100	8.1%
599 Lexington Avenue, Floor 21		
New York, NY 10022		
AIGH Capital Management LLC, AIGH Investment Partners LLC and Orin Hirschman (2)	614,000	8.1%
6006 Berkeley Avenue		
Baltimore, MD 21209		
Cowen Prime Advisors (3)	593,133	7.8%
599 Lexington Avenue, Floor 21		
New York, NY 10022		
The Hewlett Fund LP (4)	523,887	6.9%
100 Merrick Road, Suite 400W		
Rockville Centre, NY 11570		
Larry Lytton (5)	521,691	6.9%
467 Central Park West		
New York, NY 10025		
Directors and named executive officers		
John L. Lubniewski (6)	123,225	1.6%
Shaun D. McMeans (7)	54,567	*
Byron Lawson (8)	28,196	*
Ann Hanham (9)	6,884	*
Harry A. George (10)	18,757	*
Michelle R. Griffin (11)	6,165	*
Donnie M. Hardison (12)	7,631	*
James T. LaFrance (13)	7,631	*
Lee McCracken (14)	7,131	*
All current executive officers and directors as a group (9 persons) (15)	260,187	**3.3%**

* Represents beneficial ownership of less than one percent.

(1) 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 590,000 shares of the Company's common stock and Mr. Wiener reports having sole voting power over an additional 25,100 shares of the Company's common stock. This information is based on the Schedule 13G filed on February 8, 2022 with the SEC.

(2) AIGH Capital Management, LLC, a Maryland limited liability company, AIGH Investment Partners, LLC, a Delaware limited liability company, and Orin Hirschman, Managing Member of AIGH Investment Partners, LLC and president of AIGH Investment Partners, LLC have reported shared voting power over 614,000 shares of Company's common stock. This information is based on the Schedule 13G filed on February 11, 2022 with the SEC.

(3) Cowen Prime Advisors LLC ("CPA") is a registered investment adviser under the Investment Advisers Act of 1940. 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 593,133 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 third quarter 2021 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, 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 9, 2022 with the SEC.

(4) The Hewlett Fund LP may be deemed to be the beneficial owner of 523,887 shares of the Company's common stock. This information is based on the Schedule 13G filed on January 4, 2022 with the SEC.

(5) Laurence W. Lytton may be deemed to be the beneficial owner of 521,691 shares, including 519,259 shares for which he has reported sole voting and dispositive power over and 2,432 shares for which he has reported shared voting and dispositive power of the Company's common stock. This information is based on the Schedule 13G filed on February 15, 2022 with the SEC.

(6) Includes 111,591 shares that Mr. Lubniewski has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options and the vesting of RSUs.

(7) Includes 46,245 shares that Mr. McMeans has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options and the vesting of RSUs.

(8) Includes 24,364 shares that Mr. Lawson has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options and the vesting of RSUs.

(9) Includes 6,398 shares that Dr. Hanham has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options.

(10) Consists of (i) 9,624 shares beneficially owned by Solstice Capital II LP and (ii) 6,532 shares that Mr. George has the right to acquire from us within 60 days of February 28, 2022 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.

(11) Includes 5,999 shares that Ms. Griffin has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options.

(12) Includes 6,798 shares that Mr. Hardison has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options.

(13) Includes 6,798 shares that Mr. LaFrance has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options.

(14) Includes 6,798 shares that Mr. McCracken has the right to acquire from us within 60 days of February 28, 2022 pursuant to the exercise of stock options.

(15) The number of shares beneficially owned consists of (a) the shares described in Notes (6) through (14).

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, 2020 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 2021 and 2020.

	December 31,	
	2021	2020
Fee Category		
Audit fees (1)	$ 409,889	$ 501,000
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total fees	$ 409,889	$ 501,000

(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 (incorporated by reference to Exhibit 4.2 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 25, 2021).
4.3	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).
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	Form of Pre-Funded Warrant issued on March 21, 2022 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the SEC on March 21, 2022).
4.9	Form of Common Stock Warrant (24-month term) issued on March 21, 2022 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the SEC on March 21, 2022).
4.10	Form of Common Stock Warrant (66-month term) issued on March 21, 2022 (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the SEC on March 21, 2022).
4.11	Registration Rights Agreement, dated as of March 17, 2022 between the Registrant and the purchaser party thereto (incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the SEC on March 21, 2022).
4.12	Description of Common 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).

Exhibit Number	Description
10.2+	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).
10.3+	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).
10.4+	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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	HTG Molecular Diagnostics, Inc. Amended and Restated 2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37369), filed with the Commission on August 19, 2021).
10.10	HTG Molecular Diagnostics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-258977), filed with the Commission on August 20, 2021).
10.11	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the HTG Molecular Diagnostics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-258977), filed with the Commission on August 20, 2021).
10.12	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the HTG Molecular Diagnostics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-258977), filed with the Commission on August 20, 2021).
10.13	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).
10.14+	HTG Molecular Diagnostics, Inc. Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 25, 2021).
10.15+	HTG Molecular Diagnostics, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 25, 2021).
10.16+	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).
10.17+	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).

Exhibit Number	Description
10.18+	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).
10.19	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).
10.20	Second Amendment to Lease Agreement (Suite 300 – Laboratory), dated December 8, 2020, by and between the Registrant and Pegasus Properties, L.P. (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 25, 2021).
10.21	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).
10.22	Third Amendment to Lease Agreement (Suite 100 – Administration), dated December 8, 2020, by and between the Registrant and Pegasus Properties, L.P. (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-37369), filed with the SEC on March 25, 2021).
10.23	Third Amendment, dated September 27, 2021, to Standard Commercial-Industrial Multi Tenant Triple Net Lease, dated July 11, 2008, between the Company and Pegasus Properties L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 0001-37369), filed with the SEC on September 29, 2021).
10.24	Fourth Amendment, dated September 27, 2021, to Standard Commercial-Industrial Multi Tenant Triple Net Lease, dated May 11, 2011, between the Company and Pegasus Properties L.P. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 0001-37369), filed with the SEC on September 29, 2021).
10.25	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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

+ Indicates management contract or compensatory plan.

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 29, 2022

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 (Principal Executive Officer)	March 29, 2022
/s/ Shaun D. McMeans Shaun D. McMeans	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	March 29, 2022
/s/ Laura L. Godlewski Laura L. Godlewski	Senior Vice President of Finance and Administration (Principal Accounting Officer)	March 29, 2022
/s/ Ann F. Hanham Ann F. Hanham	Chair of Board of Directors	March 29, 2022
/s/ Harry A. George Harry A. George	Director	March 29, 2022
/s/ Michelle R. Griffin Michelle R. Griffin	Director	March 29, 2022
/s/ Donnie M. Hardison Donnie M. Hardison	Director	March 29, 2022
/s/ Christopher P. Kiritsy Christopher P. Kiritsy	Director	March 29, 2022
/s/ James T. LaFrance James T. LaFrance	Director	March 29, 2022
/s/ Lee R. McCracken Lee R. McCracken	Director	March 29, 2022

Exhibit 4.12

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 previously designated 51,270 shares of preferred stock as Series A Convertible Preferred Stock ("Series A Preferred"), of which 23,770 shares are issued and outstanding as of the end of the period covered by 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. Each share of Series A Preferred that is converted into common stock resumes the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series A Preferred.

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; provided, however, the foregoing forum selection provisions do not apply to actions arising under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended; 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.

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 (No. 333-262357) and Form S-8 (Nos. 333-203930, 333-208325, 333-210401, 333-216942, 333-222571, 333-229303, 333-231349, 333-235961, 333-248207, 333-252142 and 333-258977) of HTG Molecular Diagnostics, Inc. of our report dated March 29, 2022, 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 29, 2022

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, 2021 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 29, 2022

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, 2021 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 29, 2022

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 year ended December 31, 2021 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 29, 2022

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 year ended December 31, 2021 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 29, 2022

By: /s/ Shaun D. McMeans

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