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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 6, 2021

HTG Molecular Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-37369	86-0912294
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS 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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, $0.001 par value per share	**HTGM**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

As previously announced on January 5, 2021, our full year 2020 revenue is expected to be approximately $8.5 million. The corporate presentation furnished as Exhibit 99.1 to this Current Report contains a breakdown of this total revenue amount by direct revenue and collaboration revenue, as described therein. These results are preliminary and unaudited, are based on management's initial review of our results for the year ended December 31, 2020 and are subject to revision based upon our year-end closing procedures and the completion and external audit of our year-end financial statements. Actual results may differ from these preliminary unaudited results as a result of the completion of year-end closing procedures, final adjustments and other developments arising between now and the time that our financial results are finalized, and such changes could be material. In addition, these preliminary unaudited results are not a comprehensive statement of our financial results for the year ended December 31, 2020, should not be viewed as a substitute for full, audited financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of our results for any future period.

Item 7.01 Regulation FD Disclosure.

Included as Exhibit 99.1 to this Current Report on Form 8-K is our corporate presentation, dated January 2021, which is incorporated herein by reference. We intend to utilize this presentation and its contents in various meetings with securities analysts, investors and others in connection with the Annual J.P. Morgan Healthcare Conference, commencing January 6, 2021.

The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation

SIGNATURES

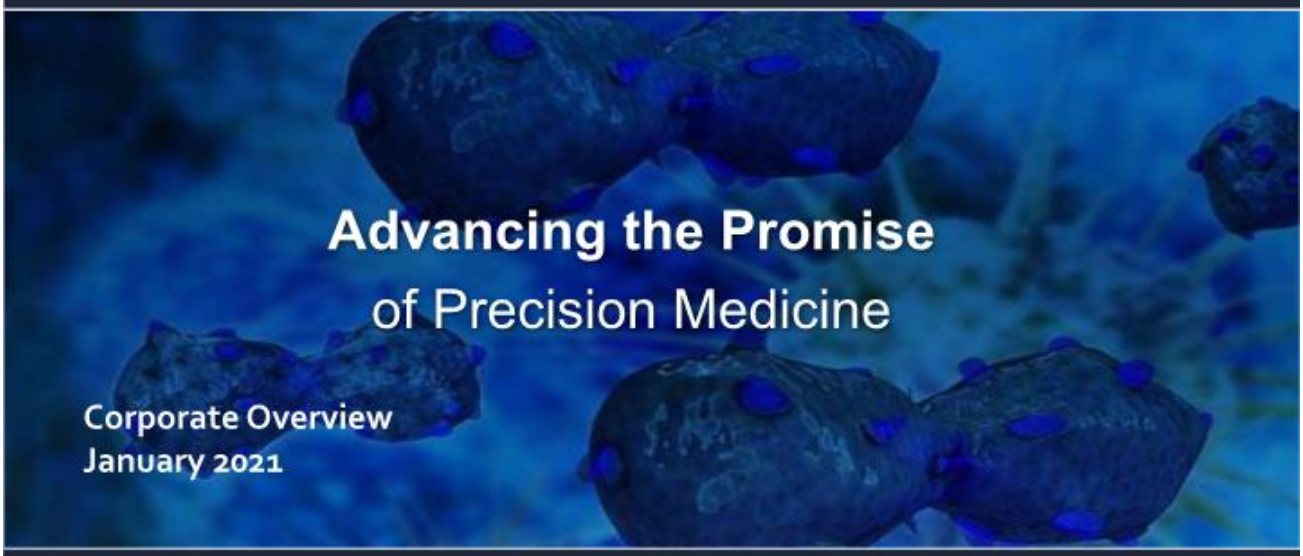
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HTG Molecular Diagnostics, Inc.

Dated: January 6, 2021

By: /s/ Shaun D. McMeans
Shaun D. McMeans
Senior Vice President and Chief Financial Officer

Exhibit 99.1



HTG Molecular

Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our transactions with biopharmaceutical companies, possible companion diagnostic and HTG Molecular Diagnostics, Inc. ("HTG") diagnostic products, potential addressable markets and the size of those markets, our timeline strategy, planned product development and our product and technology roadmap, expected regulatory submissions and filings, anticipated reimbursement, prospects, and plans and objectives are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in forward-looking statements, including due to risks and uncertainties associated with the development and commercialization of products, competition with new and existing technologies, the outcome of relationships with third parties, the COVID-19 pandemic and other factors as discussed under the heading "Risk Factors" in our periodic reports on Form 10-Q and Form 10-K. The forward-looking statements contained in this presentation reflect our views with respect to future events as of the date set forth on the first page of this presentation, and we assume no obligation to update any forward-looking statements as a result of new information, future events or otherwise as of such date.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our products, product candidates and services, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. These statements are based upon information available to us as of the date of the presentation, 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, and you are cautioned not to unduly rely upon these statements.

Enabling precision medicine with gene expression profiling in three market segments

HTG EdgeSeq

Proprietary technology platform for NGS RNA gene-expression profiling (GEP) serving the full precision medicine value-chain

Translational profiling

NGS GEP publications have **doubled to >10K annually over the last 5 years**, immuno-oncology is a major driver

Drug development

Leading biopharma customers using **RNA biomarkers** to drive development of potential **targeted therapies**

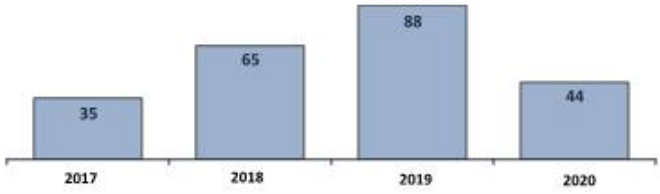
Clinical diagnostics

MDx companies are conducting **massively scaled NGS GEP** for new test R&D and major cancer centers are building LDT's

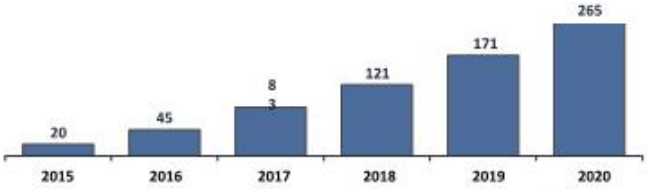
COVID impacted growth timeline but market drivers remain

HTG revenue growth

HTG growth in active clinical biopharma programs



Growth in cumulative publications on HTG EdgeSeq



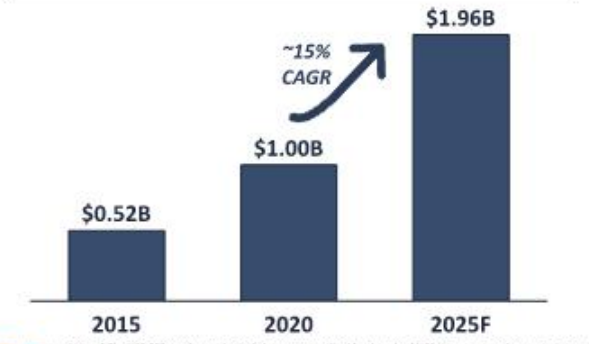
Notes: * Direct revenue include all products and services provided by HTG directly; does not include partnered collaboration revenues; ** Company analysis; + preliminary and unaudited, subject to change based on year-end closing procedures and external audit.

Target markets are large and fast growing

Translational profiling

BioPharma Services

NGS GEP tools supplier market*



Notes: * The NGS GEP supplier market includes revenue realized for the sale of NGS instruments and reagents that are used for GEP
Source: Decillio Consulting

Oncology clinical trials leveraging GEP

Notes: * Only oncology (hematological and solid tumors) interventional trials measuring at least one drug (devices and surgery excluded), all sponsor types, with and without RNA / Gene expression biomarkers
Source: Amplion; Contract Consultants

Clinical diagnostics market

+

Major Cancer Centers in the US and Europe

72 NCI centers in the US
42 OECI centers in Europe

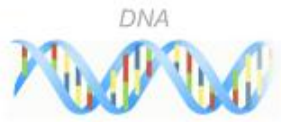
Major Dx Content Providers

CARIS · TEMPUS · EXACT SCIENCES · veracyte · CASTLE · Personalis · sema4 · NEO · DECIPHER BIOSCIENCES · AGENDIA · myriad · Adaptive · GUARDANT · mirvie · ASPIRA · NantOmics · BGI · CareDx · Invitae

HTG

Source – Cancer.gov, OECI.eu

Gene expression profiling (GEP) is a cornerstone biomarker for precision medicine



GEP complements mutation information that is only part of the puzzle for precision medicine

RNA

GEP measures aberrations in the abundance of gene transcripts to drive precision medicine

Protein

GEP advantaged over protein expression: multiplexing, integration with mutation workflow, quantitation

Fundamental aspect of biology | Countless applications

Examples

Prognostic testing
Oncogene expression-based risk stratification emerging across all major cancer types

Molecular sub-typing
Improve tumor classification (e.g., CUP, DLBCL) as orthogonal or replacement to histology

Tumor inflammation
Also called hot vs. cold tumors; factors into likelihood of response across variety of IO drug types

CAR-T
Profiling to ensure quality across the workflow, from leukapheresis through cell expansion & infusion

New horizons
Emerging autoimmune / neurology applications; miRNA signatures for prognosis, screening, and beyond

HTG's EdgeSeq designed to redefine RNA-seq for GEP

Traditional RNA-seq

Great for mutation detection, inefficient for RNA GEP

EdgeSeq

Purpose-built for high-performance GEP

Increased sensitivity	Simplified workflow	Cutting-edge performance
5 – 10X less starting sample required	*Avoids complex & biased RNA-seq workflow steps*	*Clinical-grade assay quality designed for high-value CDx*
Compatible with both liquid & tissue samples	*Turn-around-time of 3 days vs. 7 days or more*	*Low failure rate and high dynamic range*
Maintains effectiveness with degraded samples	*Bioinformatics in <1 hour vs. 4 – 8 hours or more*	*High-plex (up to 4K) panels, transcriptome expected Q3 2021*

HTG

Hybrid commercial strategy – products and services

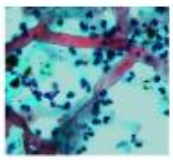
Hybrid commercial strategy

Biopharma services

Instruments & kits

Translational profiling

Targeted panels drive HTG's translational profiling

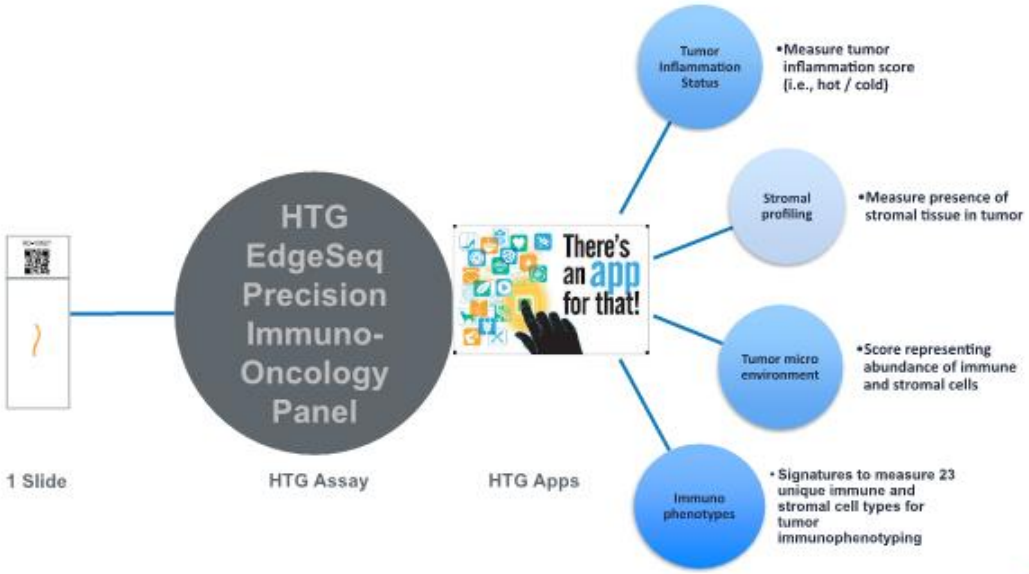


- **HTG EdgeSeq™ Precision Immuno-Oncology Panel**
  1,392 immuno-oncology related genes; Key immune system markers (B & T cell activation & response)
- **HTG EdgeSeq™ Oncology Biomarker Panel**
  2,560 oncology-related genes – drug targets / signaling pathways; Whole transcriptome surrogate
- **HTG EdgeSeq™ ALKPlus Assay (CE IVD)**
  ALK, ROS1, RET, NTRK1, HER2 ins, cMET amplifications
- **HTG EdgeSeq™ DLBCL COO Assay (CE IVD)**
  ABC / GCB subtyping; 92 lymphoma genes plus drug targets
- **HTG EdgeSeq™ miRNA Whole-Transcriptome Assay**
  2,083 human miRNA - analysis using a variety of samples
- **HTG EdgeSeq™ Immune Response Panel**
  2,003 genes to assess a variety of autoimmune diseases
- **HTG EdgeSeq™ Mouse mRNA Tumor Panel**
  1,659 mRNA targets for preclinical mouse models
- **HTG EdgeSeq™ Pan B-Cell Lymphoma Panel**
  298 mRNA targets to identify lymphoma subgroups

HTG's Reveal software simplifies bioinformatics

- Web-based statistical analysis packages
- Visualizes complex gene expression profiles
- All sessions are encrypted and protected to preserve privacy and integrity of data
- All analyses and outputs can be saved and archived locally

Reveal applications – like a smartphone, one assay with many applications



BioPharma services

Biopharma services

Strategy

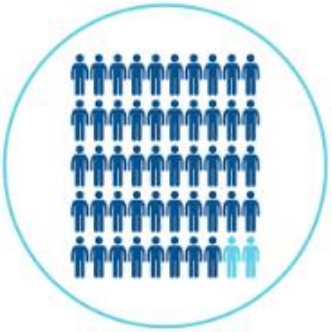
Become the platform technology of choice for RNA GEP biomarker development

Leverage that into pharma collaborations for CDx opportunities

Collaborations are pharma sponsored 'shots on goal' for a clinical app

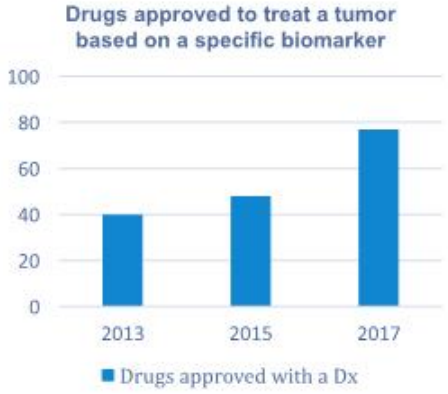
44 Active Biopharma Programs – December 31, 2020

- Net decline of 44 programs since January 1, 2020
  - 63 'timed out'
  - 25 extended
  - 19 new programs
- 9 new customers
- COVID impacted Biopharma services



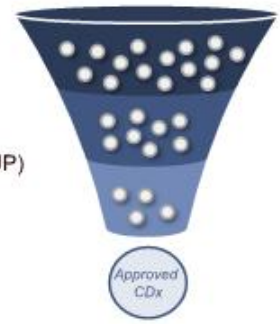
HTG

Market drivers remain in place for Biopharma services



Revenue opportunity for a CDx

One front line CDx in a 100k incidence rate cancer represents a potential $30M/yr revenue opportunity (assuming $300/test AUP)



HTG

Notes: * Only oncology (hematological and solid tumors) interventional trials measuring at least one drug (devices and surgery excluded), all sponsor types, with and without RNA / Gene expression biomarkers
Source: Ampliors Contract Consultants

Clinical diagnostics

WTTx – the next step for HTG

Enable a global system biology view with EdgeSeq benefits

Targeted panels – 1 – 3k genes

WTTx – whole transcriptome, 20k+ genes

Opportunities for WTTx

Position as a full transcriptome alternative to RNASeq

- Leverage EdgeSeq technical advantages
- Leverage EdgeSeq's ease of use
- Leverage EdgeSeq's simple bioinformatics

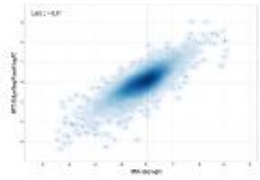
Position as a universal CDx platform for biopharma

- WTTX is intended to uniquely enable NGS GEP CDx, RNA-seq is seen as not clinically deployable
- HTG's instruments and kits enable a distributed model
- HTG's QIAGEN Distribution Agreement facilitates global market access options

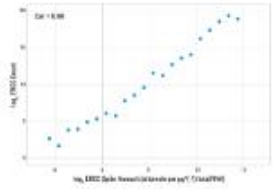
Position as a platform technology for other test developers

- Enables NGS GEP diagnostics in a centralized CLIA and decentralized IVD setting
- Low sample input enables GEP to be done in parallel with mutation profiling with other assays
- EdgeSeq advantages (e.g., ease-of-use, workflow, bioinformatics) vs alternatives (RNA-Seq)
- No chemistry or workflow changes from R&D through commercialization

WTTx transcriptome: Critical milestone achievement – technical feasibility, October 2020



Comparison of differential expression analysis results between the prototype HTG whole transcriptome panel and RNA-Seq using two breast cancer subtypes. Differential expression of genes determined using RNA-Seq (x-axis) and HTG EdgeSeq Whole Transcriptome Prototype Panel (y-axis) demonstrated good directional alignment with the Lin's concordance correlation coefficient value of 0.77.

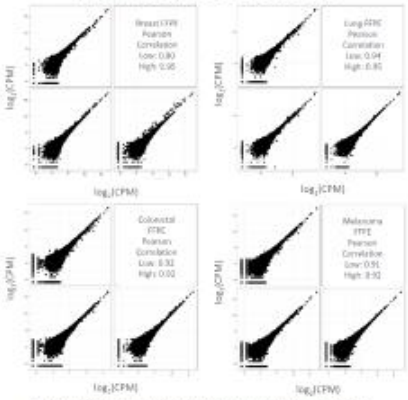


The relationship between signal and abundance for ERCC spike-in controls. The $\log_2$-transformed signal for the ERCC transcripts are plotted on the y-axis vs ERCC spike-in amount on the x-axis. The Pearson correlation coefficient was determined to be 0.99. These data demonstrate linear response of the panel across the dynamic range spanning ~20 orders of magnitude on a $\log_2$ scale.

HTG has demonstrated that the EdgeSeq technology is highly scalable, and allows measurement of the entire human transcriptome, while maintaining all of its advantages, such as less sample input, extraction-free chemistry, and ability to test low-quality FFPE tissue or extracted RNA.

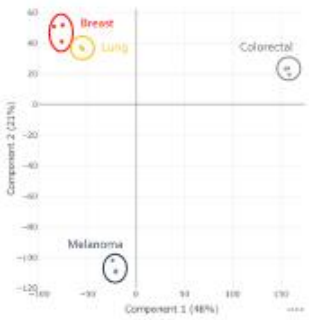
January update – technical feasibility results

High Assay Reproducibility



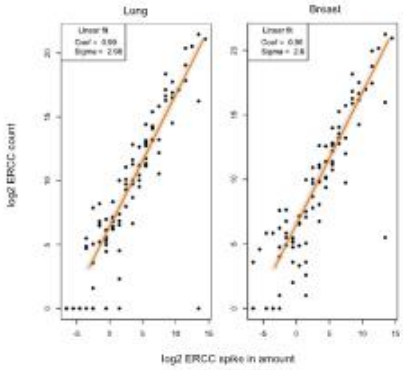
Conclusion: Melanoma, breast, lung, and colorectal cancer tissue samples were run in triplicate. Pearson correlation coefficients between individual replicates ranged from 0.90 to 0.95 indicating high level of reproducibility.

Discrete Clustering by Indication



Conclusion: Principal Components Analysis clusters replicates from same cancer indication together, but away from other cancer types. These data indicate assay's ability to detect differential expression in different tissue types, resulting in discrete clustering in multi-dimensional space.

Exceptional Accuracy



Conclusion: RNA Control (ERCC) Transcripts were used to demonstrate that assay signal generated by panel is proportional to, and highly correlated with, amount of ERCC material spiked into the sample (Pearson correlation coefficients are 0.99 in lung and 0.96 in breast tissue). Data also illustrate that the response is linear across 10^6-fold concentration range covered by ERCC controls.

HTG

2021 HTG WTTx development milestones

Target Customer Segments

Translational profiling

Investigators using gene expression data in oncology, immune response, transplant and other disease areas

Drug development

Leading biopharma using gene expression to develop precision medicines

Clinical diagnostics

MDx companies and CLIA laboratories in large academic medical centers using gene expression for LDT's

Key Growth Strategies