
**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

November 10, 2020
Date of Report (Date of earliest event reported)

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

Delaware
(State or other jurisdiction
of incorporation)

001-37369
(Commission
File Number)

86-0912294
(IRS Employer
Identification No.)

3430 E. Global Loop
Tucson, AZ
(Address of principal executive offices)

85706
(Zip Code)

Registrant's telephone number, including area code: (877) 289-2615

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.

On November 10, 2020, HTG Molecular Diagnostics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2020. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the attached exhibit are being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release of HTG Molecular Diagnostics, Inc. dated November 10, 2020

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: November 10, 2020

By: /s/ Shaun D. McMeans
Shaun D. McMeans
SVP and Chief Financial Officer

FOR IMMEDIATE RELEASE

HTG Molecular Diagnostics Reports Third Quarter 2020 Results

Call scheduled for today, November 10, at 4:30pm ET

TUCSON, Ariz., November 10, 2020 -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a life science company whose mission is to advance precision medicine, today reported its financial results for the quarter ended September 30, 2020.

Recent Business Highlights

- Released HTG EdgeSeq Reveal version 3.0, adding additional software functionalities, including analytic capabilities for use with HTG's entire RUO profiling assay menu and new RUO oncology applications. HTG EdgeSeq Reveal, originally launched in January 2019, is a web-based biostatistical analysis software suite designed to accelerate customer research by streamlining statistical analysis of samples processed with HTG's RUO profiling assays.
- Entered into a 10-year Commercialization and Distribution Agreement (Master Agreement) with QIAGEN Manchester Limited (QIAGEN), providing the foundation for HTG and QIAGEN to combine their technological and commercial strengths with the goal to offer pharmaceutical companies global development, distribution and commercialization capabilities for companion diagnostic assays developed on the HTG EdgeSeq platform.

"As the impact of COVID-19 placed continued pressure on our core oncology business, including planned studies and laboratory operations of our customers in the third quarter of 2020, we continued to make strategic shifts in our business into areas less impacted by the pandemic," said John Lubniewski, President and CEO of HTG. "We also believe strategic adjustments made over the past several months to lessen the impact of COVID-19 on our business are working. These efforts have focused on customer diversification to include a larger number of smaller and mid-sized biopharma customers and academic medical centers who have shown signs of returning to work more quickly than our larger customers. We are also targeting the large immune response market, which is often a new call point with our current customer base. Immune response target markets include, but are not limited to, autoimmune disorder and infectious disease. The ultimate impact of COVID-19 remains uncertain, but we are seeing positive trends in non-oncology opportunities and believe direct revenue from our core oncology business will begin to recover to pre-COVID levels in the first half of next year."

Mr. Lubniewski continued, "Our product development team continued to perform on our key milestones during the quarter. We have produced our first white paper on technical feasibility for our approximately 20,000 gene whole transcriptome (WTTx) HTG EdgeSeq panel, and we believe we remain on track to delivering upcoming development and commercialization milestones as well. We have positioned ourselves through careful cost savings, strategic initiatives and a continued focus on strengthening our technology to meet demand and to grow when we and our customers are able to return to normal operations."

Third Quarter 2020 Financial Highlights:

Total revenue for the quarter ended September 30, 2020 was \$1.8 million, compared with \$5.4 million for the same period in 2019. The decrease in revenue is a result of the impact of the COVID-19 pandemic requiring the closure of customer facilities or continuing to limit the ability of our customers to operate at pre-pandemic levels.

Product and product-related services revenue was \$1.7 million for the quarter ended September 30, 2020, compared with \$4.3 million for the same period in 2019. Throughout the pandemic, HTG's ability to ship instruments and consumables to customer facilities and the ability of its customers to prepare and ship samples to HTG's VERI/O laboratory for processing has been limited. In addition to the impacts of the COVID-19 pandemic, this decrease reflects a decline in lower margin subcontracted laboratory services revenue when compared with the third quarter of 2019.

Collaborative development services revenue for the quarter ended September 30, 2020 was \$0.1 million compared with \$1.1 million for the same period in 2019, reflecting the completion of remaining procedures under existing arrangements and ongoing sales efforts to identify and contract new programs in this area.

Net loss from operations for the quarter ended September 30, 2020 was \$5.2 million, compared with \$4.6 million for the third quarter of 2019. Net loss per share was \$(0.07) for the third quarter of 2020 compared with \$(0.15) for the third quarter of 2019.

Cash, cash equivalents and short-term available-for-sale securities totaled \$30.5 million as of September 30, 2020, with current liabilities of approximately \$6.0 million and non-current liabilities of \$14.5 million.

Conference Call and Webcast:

HTG will host a conference call for the investment community today beginning at 4:30 p.m. Eastern Time. Conference call and webcast details are as follows:

Date:	Tuesday, November 10, 2020
Time:	4:30 p.m. Eastern Time
Toll Free:	(877) 407-0789
International:	(201) 689-8562
Conference ID:	13711846
Webcast:	http://public.viaavid.com/index.php?id=141926

About HTG:

HTG is focused on NGS-based molecular profiling. The company's proprietary HTG EdgeSeq technology automates complex, highly multiplexed molecular profiling from solid and liquid samples, even when limited in amount. HTG's customers use its technology to identify biomarkers important for precision medicine, to understand the clinical relevance of these discoveries, and ultimately to identify treatment options. Its mission is to empower precision medicine.

Safe Harbor Statement:

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential benefits of the Master Agreement with QIAGEN, the anticipated duration of the impact of the COVID-19 pandemic on our business, our being on track to deliver development milestones, our belief that direct revenue from our core oncology business will begin to recover to pre-COVID levels in the first half of next year, and our expectations for increased demand for our products and services in the future and our ability to meet those demands and for growth in our business. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based upon management's current expectations, are subject to known and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation, risks associated with the impact of the COVID-19 pandemic on us and our customers; the risk that we may not establish new and significant collaboration development arrangements; risks associated with our ability to develop and commercialize our products, including our WTTx product; the risk that our products and services may not be adopted by biopharmaceutical companies or other customers as anticipated, or at all; our ability to manufacture our products to meet demand; the level and availability of

third party payor reimbursement for our products; our ability to protect our intellectual property rights and proprietary technologies; our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; competition in our industry; additional capital and credit availability; our ability to attract and retain qualified personnel; and product liability claims. These and other factors are described in greater detail in our filings with the Securities and Exchange Commission, including without limitation our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. All forward-looking statements contained in this press release speak only as of the date on which they were made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contact:

Ashley Robinson
Phone: (617) 430-7577
Email: arr@lifesciadvisors.com

-Financial tables follow-

HTG Molecular Diagnostics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Product and product-related services	\$ 1,701,068	\$ 4,311,043	\$ 5,417,731	\$ 11,397,916
Collaborative development services	76,030	1,093,750	548,135	3,006,022
Total revenue	1,777,098	5,404,793	5,965,866	14,403,938
Operating expenses:				
Cost of product and product-related services revenue	940,892	2,939,007	2,931,026	7,492,905
Selling, general and administrative	4,752,321	4,516,341	13,683,069	13,657,917
Research and development	1,255,416	2,570,355	4,914,467	7,898,742
Total operating expenses	6,948,629	10,025,703	21,528,562	29,049,564
Operating loss	(5,171,531)	(4,620,910)	(15,562,696)	(14,645,626)
Other income (expense), net	(238,676)	(123,000)	(482,599)	(259,552)
Loss on extinguishment of MidCap Credit Facility and QNAH Convertible Note	—	—	(522,394)	—
Net loss before income taxes	(5,410,207)	(4,743,910)	(16,567,689)	(14,905,178)
Benefit from (provision for) income taxes	(1,581)	3,678	(12,548)	(3,170)
Net loss	\$ (5,411,788)	\$ (4,740,232)	\$ (16,580,237)	\$ (14,908,348)
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.15)	\$ (0.25)	\$ (0.50)
Shares used in computing net loss per share, basic and diluted	72,323,436	31,367,044	67,567,031	29,551,836

HTG Molecular Diagnostics, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,884,468	\$ 7,619,748
Short-term investments available-for-sale, at fair value	11,632,160	25,410,222
Restricted cash	—	3,270,247
Accounts receivable	1,370,201	3,164,176
Inventory, net	1,538,553	1,269,667
Prepaid expenses and other	946,979	633,522
Total current assets	34,372,361	41,367,582
Operating lease right-of-use assets	746,185	1,209,145
Property and equipment, net	1,526,698	2,240,133
Other non-current assets	64,861	302,409
Total assets	\$ 36,710,105	\$ 45,119,269
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 875,236	\$ 1,662,583
Accrued liabilities	1,386,825	1,870,296
Contract liabilities - current	348,274	426,014
NuvoGen obligation - current	645,949	1,152,233
Short-term debt, net	2,266,884	2,987,667
Operating lease liabilities - current	436,663	758,932
Other current liabilities	26,620	41,134
Total current liabilities	5,986,451	8,898,859
NuvoGen obligation - non-current, net of discount	4,455,968	4,498,777
Long-term debt, net	9,446,985	6,871,545
Operating lease liabilities - non-current	390,233	636,340
Other non-current liabilities	229,114	244,114
Total liabilities	20,508,751	21,149,635
Commitments and Contingencies		
Total stockholders' equity	16,201,354	23,969,634
Total liabilities and stockholders' equity	\$ 36,710,105	\$ 45,119,269