
**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 12, 2019
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))

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.

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

Item 2.02 Results of Operations and Financial Condition

On November 12, 2019, HTG Molecular Diagnostics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. 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 12, 2019

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.

Dated: November 12, 2019

HTG Molecular Diagnostics, Inc.

By: /s/ Shaun D. McMeans

Shaun D. McMeans

SVP and Chief Financial Officer

FOR IMMEDIATE RELEASE

HTG Molecular Diagnostics Reports Third Quarter 2019 Results

Product and product-related services revenue increased by 228% and 125% in the three and nine-month periods, respectively, compared to the prior year periods

Call scheduled for today, November 12, at 4:30pm ET

TUCSON, Ariz., November 12, 2019 -- HTG Molecular Diagnostics, Inc. (Nasdaq:HTGM) (HTG), a diagnostic company whose mission is to advance precision medicine, today reported its financial results for the third quarter ended September 30, 2019.

Recent Accomplishments & Highlights:

- Achieved product and product-related services revenue of \$4.3 million and \$11.4 million for the three and nine-month periods ended September 30, 2019, respectively, representing increases of 228% and 125% over the respective periods in 2018. This increase reflects additional instrument placements in the United States and Europe, increased RUO consumables product sales stemming from the expansion of the company's menu of RUO assays and programs with an expanding number of biopharmaceutical company customers.
- Launched a new 2,002-gene HTG EdgeSeq Autoimmune Profiling Assay for purchase as a kit or as a service in HTG's VERI/O laboratory at the end of October 2019.
- Hosted a Key Opinion Leader ("KOL") Meeting in October 2019 highlighting the company's new Molecular Diagnostics offerings and the potential opportunity in breast cancer. Thought leaders discussed the unmet medical need in breast cancer, and the company unveiled its strategic plan and detailed development plan for new assays with the goal of improving patient care.
- Completed a financing transaction generating net proceeds of approximately \$20.7 million after deducting underwriting discounts and commissions and offering expenses. In a registered offering, HTG issued 29,298,537 shares of its common stock and in a concurrent private placement issued pre-funded warrants to purchase 5,411,687 shares of common stock.
- Provided notice of termination, effective immediately, of the company's Master Assay Development, Commercialization and Manufacturing Agreement with QIAGEN Manchester Limited ("QIAGEN").

"Our RUO profiling business continues to grow in both the BioPharma and Academic markets. In BioPharma we are seeing growth in both the number of programs and in the number of customers. We are optimistic we will continue to see strength in this business segment. However, across our RUO profiling business generally we have recently had a couple of key projects slip from expected fourth quarter execution into planned 2020 projects," said John Lubniewski, President and CEO of HTG. "Collaborative development services revenue continues to be our most significantly impacted revenue stream, as a result of reduced activity in our two existing PDP development programs, as well as a lack of new programs. While we remain positive about the long-term potential of this line of business and our ability to grow it in the future, our near-term business has unfortunately been impacted by QIAGEN's multiple, recent announcements reflecting a rapid and premature shift away from

our mutual collaboration, including QIAGEN's announcement that it has stopped all development of their clinical sequencer. As a result, we are lowering our annual guidance."

Mr. Lubniewski continued, "As outlined during our KOL meeting in October, we are focused on building a proprietary molecular diagnostics business with a strategic focus in both high plex clinical grade RUO panels as well as clinical breast cancer assays. We believe our technology has the potential to fundamentally change breast cancer diagnostic testing as well as RNA-based RUO profiling, and we look forward to supporting development in this exciting new area."

Third Quarter 2019 Financial Results:

Total revenue for the three and nine-month periods ended September 30, 2019 were \$5.4 million and \$14.4 million, respectively, an increase of 15% over the third quarter of 2018 and a 5% increase over the nine-month period ended September 30, 2018. The increase in revenue in both periods was primarily due to the growth of the company's core RUO profiling business.

Product and product-related services revenue for the three and nine-month periods ended September 30, 2019 were \$4.3 million and \$11.4 million, respectively, an increase of 228% over the third quarter of 2018 and a 125% increase over the nine-month period ended September 30, 2018. Collaborative development services revenue for the third quarter of 2019 was \$1.1 million compared to \$3.4 million in the same period in 2018.

Net loss from operations for the third quarter of 2019 was \$4.6 million, compared to \$4.8 million for the third quarter of 2018 and \$4.7 million for the second quarter of 2019. Net loss per share was \$(0.15) for the third quarter of 2019 compared to \$(0.17) for the third quarter of 2018.

HTG ended the third quarter with \$37.9 million in cash, cash equivalents and short-term available-for-sale securities and current liabilities of approximately \$8.4 million plus an additional \$14.4 million in non-current liabilities. An additional \$3.3 million of restricted cash was held in connection with a convertible note that is included in non-current liabilities as of September 30, 2019.

2019 Revenue Guidance:

The company believes that its total revenue for the full year ending December 31, 2019 will be in the range of \$19.0 to \$20.0 million.

Conference Call and Webcast:

HTG will host an investment community conference call today beginning at 4:30 p.m. Eastern Time. Conference call and webcast details follow:

Date:	Tuesday, November 12, 2019
Time:	4:30pm Eastern Time
Toll Free:	(877) 407-0789
International:	(201) 689-8562
Conference ID:	13695647
Webcast:	http://public.viavid.com/index.php?id=136602

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 our expected performance, growth of various lines of business, the potential of our technology to fundamentally change breast cancer diagnostic testing as well as RNA-based RUO profiling, and our revenue and operational expectations. 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, the risk that we may not achieve our revenue expectations for 2019; the risk that projects that we expect to occur in 2020 do not occur; the risk that we may not realize the benefits expected under our collaboration agreements; risks associated with our ability to successfully commercialize our products; 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 effectively manage our anticipated growth; 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, 2019. 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:

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-Financial tables follow-

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product and product-related services	\$ 4,311,043	\$ 1,314,844	\$ 11,397,916	\$ 5,071,702
Collaborative development services	1,093,750	3,391,534	3,006,022	8,704,094
Total revenue	5,404,793	4,706,378	14,403,938	13,775,796
Operating expenses:				
Cost of product and product-related services revenue	2,939,007	1,239,702	7,492,905	3,827,447
Selling, general and administrative	4,516,341	4,709,885	13,657,917	15,132,468
Research and development	2,570,355	3,561,459	7,898,742	8,909,729
Total operating expenses	10,025,703	9,511,046	29,049,564	27,869,644
Operating loss	(4,620,910)	(4,804,668)	(14,645,626)	(14,093,848)
Loss on settlement of Growth Term Loan	—	—	—	(105,064)
Interest income (expense), net	(123,000)	(38,740)	(259,552)	(123,627)
Net loss before income taxes	(4,743,910)	(4,843,408)	(14,905,178)	(14,322,539)
Provision for income taxes	3,678	—	(3,170)	(3,545)
Net loss	\$ (4,740,232)	\$ (4,843,408)	\$ (14,908,348)	\$ (14,326,084)
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.17)	\$ (0.50)	\$ (0.53)
Shares used in computing net loss per share, basic and diluted	31,367,044	28,434,406	29,551,836	27,184,968

HTG Molecular Diagnostics, Inc.
Consolidated Balance Sheets

	September 30, 2019	December 31, 2018
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 34,847,086	\$ 8,432,600
Short-term investments available-for-sale, at fair value	3,037,393	22,681,049
Accounts receivable	3,933,361	5,012,678
Inventory, net	1,191,742	1,306,609
Prepaid expenses and other	854,632	519,002
Total current assets	<u>43,864,214</u>	<u>37,951,938</u>
Restricted cash	3,270,247	3,270,247
Operating lease right-of-use assets, net	1,370,189	—
Property and equipment, net	2,183,443	2,373,790
Other non-current assets	239,713	175,305
Total assets	<u>\$ 50,927,806</u>	<u>\$ 43,771,280</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,016,538	\$ 1,849,921
Accrued liabilities	1,795,129	3,358,465
Contract liabilities - current	306,154	332,711
NuvoGen obligation - current	1,327,922	1,290,234
MidCap Term Loan payable - current	1,166,667	—
Operating lease liabilities - current	773,376	—
Other current liabilities	34,011	186,043
Total current liabilities	<u>8,419,797</u>	<u>7,017,374</u>
NuvoGen obligation - non-current, net of discount	4,650,924	5,702,519
Convertible note - net of debt issuance costs	2,984,304	2,974,213
MidCap Term Loan payable - non-current, net of discount and debt issuance costs	5,654,410	6,704,641
Operating lease liabilities - non-current, net of discount	820,888	—
Other non-current liabilities	280,979	280,471
Total liabilities	<u>22,811,302</u>	<u>22,679,218</u>
Commitments and Contingencies		
Total stockholders' equity	<u>28,116,504</u>	<u>21,092,062</u>
Total liabilities and stockholders' equity	<u>\$ 50,927,806</u>	<u>\$ 43,771,280</u>