
**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 8, 2018
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.

Item 2.02 Results of Operations and Financial Condition

On November 8, 2018, HTG Molecular Diagnostics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. 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 8, 2018

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 8, 2018

HTG Molecular Diagnostics, Inc.

By: /s/ Shaun D. McMeans

Shaun D. McMeans

Senior Vice President and Chief Financial Officer



HTG Molecular Diagnostics, Inc.
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FOR IMMEDIATE RELEASE

HTG Molecular Diagnostics Reports Third Quarter 2018 Results

Revenue increased 26% and 101% for the three and nine months ended September 30, 2018 compared to the respective prior year periods

Call scheduled for today, November 8, at 4:30 pm ET

TUCSON, Ariz., November 8, 2018 – HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a provider of instruments, reagents and services for molecular profiling applications, today reported financial results for the three and nine months ended September 30, 2018.

Recent Accomplishments & Highlights:

- Achieved revenue of \$4.7 million and \$13.8 million for the three and nine months ended September 30, 2018, respectively, which represents a 26% and 101% increase over the same periods in 2017, respectively.
 - Announced three amendments to the second PDP Program (SOW Two) under the Master Assay Development, Commercialization and Manufacturing Agreement (the Governing Agreement) with QIAGEN Manchester Limited (QML). Development activities for the clinical trial assay have been completed, and the amendments relate to the next phase development activities, including the use of the investigational use only (IUO) assay developed in the initial-phase in a retrospective clinical trial and in additional disease indications.
 - Entered into an amendment to the third PDP Program (SOW Three) under the Governing Agreement with QML. Initial assay development activities under SOW Three are complete, and the amendment provides for the development of an IUO assay, subsequent retrospective testing of clinical trial samples, design verification and, subject to satisfactory achievement of relevant performance and regulatory milestones, regulatory submission in the US and EU necessary for the commercialization of a companion diagnostic assay for a corresponding pharmaceutical company drug.
 - Launched the HTG EdgeSeq Precision Immuno-Oncology Panel and began delivery of orders to translational and clinical researchers working in the field of cancer immunology and/or cancer immunotherapy. This research use only profiling panel provides a large, comprehensive set of genes involved in the host immune response to tumors.
 - Announced the pre-launch introduction of the new HTG EdgeSeq Mouse miRNA Whole Transcriptome Assay (WTA) with product availability for shipment expected in the fourth quarter of 2018. The HTG EdgeSeq Mouse miRNA WTA is designed for use with disease mouse models, including oncology, to identify and quantify the expression of a wide range of miRNAs in a variety of sample types, including formalin-fixed paraffin-embedded tissue.
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- Appointed Dr. Maureen T. Cronin as HTG's new Chief Scientific Officer and Senior Vice President in November 2018. Dr. Cronin brings extensive experience in genomic technology, laboratory test and pharmaceutical company therapeutics development, as well as regulatory compliance and academic clinical research to HTG.

Third Quarter 2018 Financial Results:

Total revenue for the third quarter of 2018 was \$4.7 million, an increase of 26% over the same period in the prior year and included product and product-related services revenue of \$1.3 million and collaborative development services revenue of \$3.4 million. Revenue for the third quarter of 2017 included product and product-related services revenue of \$1.6 million and collaborative development services revenue of \$2.1 million.

Net loss from operations for the third quarter of 2018 was \$4.8 million compared to \$5.4 million for the same period in the prior year. Net loss per share was \$(0.17) for the third quarter of 2018 compared to \$(0.46) for the same period in the prior year.

HTG ended the third quarter of 2018 with \$33.8 million of cash, cash equivalents and short term, available-for-sale securities investments.

2018 Revenue Guidance:

The company believes that its total revenue for the full year ending December 31, 2018 will be in the middle of the range of its previous full year 2018 revenue guidance of \$21.0 to \$25.0 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: Thursday, November 8, 2018
Time: 4:30 p.m. Eastern Time
Toll Free: (800) 458-4121
International: (323) 794-2093
Conference ID: 5881694
Webcast: <http://public.viavid.com/index.php?id=131460>

About HTG:

HTG is focused on next generation sequencing (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. The company's mission is to empower precision medicine at the local level.

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 Precision Immuno-Oncology Panel and planned HTG EdgeSeq Mouse miRNA Whole Transcriptome Assay, 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 the Precision Immuno-Oncology panel may not function or provide benefits to our customers as expected, the risk that the HTG EdgeSeq Mouse

miRNA Whole Transcriptome Assay may not be available when expected or provide benefits to our customers as expected, the risk that we may not achieve our revenue expectations for 2018 (including, without limitation, due to variations from our expectations in the amount or timing of work we perform under one or more companion diagnostic development programs with large pharma customers, which development programs comprise an increasing portion of our business and therefore have the ability to significantly impact the timing and amount of revenue recognized in one or more fiscal periods), 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 June 30, 2018. 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.

-Financial tables follow-

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Product and product-related services	\$ 1,314,844	\$ 1,592,790	\$ 5,071,702	\$ 4,422,304
Collaborative development services	3,391,534	2,130,694	8,704,094	2,433,105
Total revenue	4,706,378	3,723,484	13,775,796	6,855,409
Cost of revenue	1,239,702	1,088,987	3,827,447	3,621,193
Gross margin	3,466,676	2,634,497	9,948,349	3,234,216
Operating expenses:				
Selling, general and administrative	4,709,885	4,258,347	15,132,468	12,910,251
Research and development	3,561,459	3,478,419	8,909,729	6,364,371
Total operating expenses	8,271,344	7,736,766	24,042,197	19,274,622
Operating loss	(4,804,668)	(5,102,269)	(14,093,848)	(16,040,406)
Loss on settlement of Growth Term Loan	—	—	(105,064)	—
Other expense, net	(38,740)	(277,834)	(123,627)	(996,593)
Net loss before income taxes	(4,843,408)	(5,380,103)	(14,322,539)	(17,036,999)
Provision for income taxes	—	743	3,545	1,023
Net loss	\$ (4,843,408)	\$ (5,380,846)	\$ (14,326,084)	\$ (17,038,022)
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.46)	\$ (0.53)	\$ (1.74)
Shares used in computing net loss per share, basic and diluted	28,434,406	11,603,617	27,184,968	9,794,651

HTG Molecular Diagnostics, Inc.
Condensed Balance Sheets

	September 30, 2018	December 31, 2017
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 6,164,005	\$ 9,968,600
Short-term investments available-for-sale, at fair value	27,613,031	—
Accounts receivable	3,361,333	6,356,268
Inventory, net of allowance of \$39,403 at September 30, 2018 and \$62,142 at December 31, 2017	1,129,092	1,180,521
Prepaid expenses and other	688,556	443,068
Total current assets	38,956,017	17,948,457
Restricted cash - non-current	3,270,247	—
Deferred offering costs	—	2,953
Deferred MidCap revolving loan costs	71,126	—
Property and equipment, net	2,614,620	3,304,890
Total assets	\$ 44,912,010	\$ 21,256,300
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 1,867,181	\$ 2,438,798
Accrued liabilities	2,530,615	3,746,786
Contract liabilities - current	273,763	665,882
NuvoGen obligation - current	593,860	496,442
Growth Term Loan payable - net of discount and debt issuance costs	—	5,793,599
Other current liabilities	199,621	200,460
Total current liabilities	5,465,040	13,341,967
NuvoGen obligation - non-current, net of discount	6,684,631	7,520,913
Convertible note, related party - net of debt issuance costs	2,970,850	2,960,760
MidCap Term Loan payable - net of discount and debt issuance costs	6,666,796	—
Other non-current liabilities	333,367	492,197
Total liabilities	22,120,684	24,315,837
Commitments and Contingencies (Note 14)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2018 and December 31, 2017, 28,479,341 shares issued and outstanding at September 30, 2018 and 13,929,763 shares issued and outstanding at December 31, 2017	28,479	13,929
Additional paid-in-capital	171,663,874	131,492,595
Accumulated other comprehensive loss	(8,882)	—
Accumulated deficit	(148,892,145)	(134,566,061)
Total stockholders' equity (deficit)	22,791,326	(3,059,537)
Total liabilities and stockholders' equity (deficit)	\$ 44,912,010	\$ 21,256,300

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