



HTG Molecular Diagnostics Reports 2017 Third Quarter Earnings

November 7, 2017

Revenue increased 307% and 87%, respectively, compared to the three and nine month periods in the prior year driven by development efforts supporting Pharma clinical programs

TUCSON, Ariz., Nov. 07, 2017 (GLOBE NEWSWIRE) -- [HTG Molecular Diagnostics](#), Inc. (NASDAQ:HTGM) (HTG), a provider of instruments, reagents and services for molecular profiling applications, today reported strengthening financial results for the three and nine month periods ended September 30, 2017.

Recent Accomplishments & Highlights:

- Achieved revenue of \$3.7 million and \$6.9 million for the three and nine months ended September 30, 2017, respectively, which represents a 307% and 87% increase over the respective periods in 2016.
- Signed a second statement of work under the company's Master Assay Development, Commercialization and Manufacturing Agreement with Qiagen Manchester Limited, (QML), and a Supplement Agreement with QML and Bristol-Myers Squibb Company (BMS); both agreements relate to a project for which HTG and QML will perform initial collaborative development services for what is expected to become a multi-stage project leading to the potential development and commercialization of an NGS-based companion diagnostic assay in support of one or more of BMS's therapeutic development and commercialization programs.
- Announced that the company's HTG EdgeSeq technology will be used, together with Illumina's next-generation sequencing (NGS) technology, in a clinical trial (Survival Prolongation by Rationale Genomics or SPRING) conducted by the Worldwide Innovative Networking (WIN) Consortium, which is investigating a novel therapeutic approach using a combination of three targeted therapies for the first line treatment of patients with advanced non-small cell lung cancer.
- Preliminary data presented by lead customer at the European Congress for Pathology indicating promising performance of the HTG EdgeSeq ALK*Plus* Assay EU as compared to current clinical standard. Also announced that the company expects to complete and file the fourth and final module of the premarket approval application (PMA) for its HTG EdgeSeq ALK*Plus* Assay in the second quarter of 2018. The first three modules of the PMA have already been submitted to the U.S. Food and Drug Administration for review.
- Announced the successful completion of an audit of the company's Quality Management System for continued ISO 13485 certification by a Canadian Medical Device Conformity Assessment System-accredited registrar, which is required by Health Canada for HTG to market *in vitro* diagnostic products in Canada.
- Announced the United States Patent and Trademark Office issued two U.S. patents to the company covering certain nuclease-protection methods of detecting single-nucleotide variants and methods of treating indeterminate nevi.
- Issued a subordinated convertible promissory note to Qiagen North American Holdings, Inc. for gross proceeds to the company of \$3.0 million.

"An intense focus on the execution of our strategy set the stage for this record quarter and we believe our momentum is accelerating," said TJ Johnson, HTG President and CEO.

Third Quarter 2017 Financial Results:

Revenue for the third quarter of 2017 was \$3.7 million, driven primarily by collaboration agreement revenue from Pharma clinical programs, which accounted for \$2.1 million of the service revenue for the quarter. Consumables revenue was \$0.4 million of the \$0.6 million of product revenue for the quarter.

Net loss from operations for the third quarter of 2017 was \$5.1 million, compared to \$6.1 million for the third quarter of 2016. Net loss per share was \$(0.46) for the third quarter of 2017 compared to \$(0.92) for the third quarter of 2016.

HTG ended the third quarter with \$9.0 million in total cash and cash equivalents.

Financial Outlook for full year 2017:

HTG is increasing its guidance for the full year 2017 revenue and now expects it to be in the range of \$10.0 million to \$13.0 million.

Conference Call and Webcast:

HTG will host an investment community conference call today beginning at 4:30 p.m. ET. Conference call, webcast and post-conference call replay details follow:

Toll Free: (877) 591-4959

International: (719) 457-2644

Conference ID: 2851102

Webcast: <http://public.viavid.com/index.php?id=126439>

Replays, Available through November 21st:

Domestic: (844) 512-2921

International: (412) 317-6671

Replay PIN: 2851102

About HTG:

Headquartered in Tucson, Arizona, the mission of HTG is to empower precision medicine at the local level. The company's HTG EdgeSeq technology, which automates highly multiplexed molecular profiling of small samples for next-generation sequencing, received its first US patent in 2014. Continuous improvements led to the 2017 launch of HTG's new direct-target sequencing chemistry for DNA analysis offered in the company's VER/O services laboratory. Additional information is available at www.htgmolecular.com.

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 partnership with Qiagen, our strategic priorities and revenue expectations for 2017. 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 realize the benefits expected under our collaboration agreements, the risk that we may not achieve our revenue expectations for 2017 (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), 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 first 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 first parties; competition in our industry; the ability of 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, 2017. 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.

Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Product	\$ 625,605	\$ 506,065	\$ 1,573,926	\$ 1,683,382
Service	3,097,879	407,836	5,281,483	1,991,567
Total revenue	3,723,484	913,901	6,855,409	3,674,949
Cost of revenue	1,088,987	1,125,009	3,621,193	2,901,455
Gross margin	2,634,497	(211,108)	3,234,216	773,494
Operating expenses:				
Selling, general and administrative	4,258,347	3,937,600	12,910,251	13,343,945
Research and development	3,478,419	1,910,116	6,364,371	6,515,808
Total operating expenses	7,736,766	5,847,716	19,274,622	19,859,753
Operating loss	(5,102,269)	(6,058,824)	(16,040,406)	(19,086,259)
Other expense, net	(277,834)	(429,618)	(996,593)	(1,275,951)
Net loss before income taxes	(5,380,103)	(6,488,442)	(17,036,999)	(20,362,210)
Provision for income taxes	743	—	1,023	4,259
Net loss	\$ (5,380,846)	\$ (6,488,442)	\$ (17,038,022)	\$ (20,366,469)
Net loss per share, basic and diluted	\$ (0.46)	\$ (0.92)	\$ (1.74)	\$ (2.92)

Shares used in computing net loss per share, basic and diluted	11,603,617	7,053,010	9,794,651	6,985,924
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HTG Molecular Diagnostics, Inc.

Balance Sheets

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,047,401	\$ 7,507,659
Short-term investments available-for-sale, at fair value	—	4,304,901
Accounts receivable	3,159,223	1,377,441
Inventory, net	1,250,763	1,511,053
Prepaid expenses and other	527,623	433,328
Total current assets	13,985,010	15,134,382
Deferred offering costs	—	49,630
Property and equipment, net	3,255,438	3,270,197
Total assets	\$ 17,240,448	\$ 18,454,209
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 2,693,238	\$ 761,663
Accrued liabilities	1,997,570	1,670,286
Deferred revenue	780,965	335,659
NuvoGen obligation - current	460,698	604,751
Term loan payable - current, net of discount and debt issuance costs of \$103,738 at September 30, 2017 and \$0 at December 31, 2016	7,363,662	6,389,782
Other current liabilities	228,779	258,850
Total current liabilities	13,524,912	10,020,991
Term loan payable - non-current, net of discount and debt issuance costs of \$0 at September 30, 2017 and \$263,378 at December 31, 2016	—	5,389,137
NuvoGen obligation - non-current, net of discount	7,709,162	8,017,356
Other non-current liabilities	523,315	619,587
Total liabilities	21,757,389	24,047,071
Commitments and Contingencies		
Total stockholders' deficit	(4,516,941)	(5,592,862)
Total liabilities and stockholders' deficit	\$ 17,240,448	\$ 18,454,209

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HTG Molecular Diagnostics, Inc.