
**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): September 21, 2018

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 8.01 Other Events.

On September 21, 2018, HTG Molecular Diagnostics, Inc. (the “Company”) and QIAGEN Manchester Limited (“QML”), a U.K. corporation and wholly owned subsidiary of QIAGEN N.V., amended the third statement of work (“SOW Three”) under the parties’ Master Assay Development, Commercialization and Manufacturing Agreement (such amendment, the “First SOW Three Amendment”).

SOW Three, dated January 12, 2018, relates to development activities for a next generation sequencing-based clinical-trial assay in connection with a sponsor project agreement between QML and a pharmaceutical company (“Pharma Three”). Initial assay development activities under SOW Three are complete, and the First SOW Three Amendment provides for the development of an investigational use only assay, subsequent retrospective testing of clinical trial samples, design verification and, subject to satisfactory achievement of relevant performance and regulatory milestones, regulatory submissions in the United States and European Union necessary for the commercialization of a companion diagnostic assay for a corresponding Pharma Three drug.

The development activities to be performed under the First SOW Three Amendment are expected to extend through the first half of the fiscal year ending December 31, 2020, with key development milestones, testing and regulatory filings occurring throughout the period. QML has agreed to pay the Company mid, single-digit millions of dollars in development fees for these remaining development activities. In addition, the Company and QML will share in any net profits (as determined under the Master Assay Development, Commercialization and Manufacturing Agreement) generated from the development activities performed under the First SOW Three Amendment on an approximately quarterly basis.

QIAGEN North American Holdings, Inc., a wholly owned subsidiary of QIAGEN N.V., owns 833,333 shares of the Company’s common stock, and holds a Subordinated Convertible Promissory Note issued by the Company in the principal amount of \$3.0 million.

Forward Looking Statements

Statements contained in this report 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 about the activities expected to occur in connection with the First SOW Three Amendment and the timing thereof, the anticipated benefits or outcomes of SOW Three, as amended, and the potential development and commercialization of a companion diagnostic assay. Words such as “believes,” “anticipates,” “plans,” “expects,” “intends,” “will,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements, though 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 activities contemplated by the First SOW Three Amendment may not be performed as expected, or at all; the risk that the work performed or to be performed under SOW Three, as amended, may not support the development and commercialization of a companion diagnostic assay; 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 report 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.

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.

Date: September 27, 2018

HTG Molecular Diagnostics, Inc.

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