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

May 16, 2023
Date of Report (Date of earliest event reported)

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

Delaware	**001-37369**	**86-0912294**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3430 E. Global Loop **Tucson, AZ**	**85706**
(Address of principal executive offices)	**(Zip Code)**

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

N/A

(Former name or former address, if changed since last report.)

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 8.01 Other Events.

Drug Discovery Engine Highlights

HTG Molecular Diagnostics, Inc. (the "Company" or "HTG") is pioneering a proprietary platform-based approach that is designed to help improve drug discovery, referred to as transcriptome-informed drug discovery and design. HTG's objective is to develop best-in-class molecules for the treatment of diseases, with the ability to apply its platform agnostically across therapy areas. At the center of this approach is HTG's proprietary RNA profiling technologies, functionally married with an advanced medicinal chemistry using a novel artificial intelligence (AI)-driven platform, allowing for the improved selection and design of molecules. Currently, the Company's most advanced discovery programs are in oncology with an emphasis on the treatment of acute myeloid leukemia (AML).

Using its proprietary platforms, HTG has successfully designed a first generation chemical library. The proportion of compounds with meaningful activity (hit rate) for this first library was approximately 25% in cell-based test system models. The Company's lead compounds target AML and have demonstrated *in vitro* efficacy both as standalone agents and in combination with current standards of care, with increased efficacy versus standard of care alone. Transcriptomic analysis of these cells revealed meaningful information that contributed to the understanding of the efficacy of the candidate molecules relative to the other compounds used as reference materials for this particular pharmacologic target. Most revealing and impressive about this outcome was that select HTG candidate molecules were found to be associated with key desirable biological differences in gene expression based on known biological pathways. These results included downregulating the expression of FLT3, a gene that is well-recognized to play a role in AML proliferation and that is also mutated in the majority of AML cases, and upregulating the expression of TET2, a known tumor suppressor gene where loss of signaling is linked to progression of this cancer. This reflects a desirable biological difference, especially when compared to the reference non-HTG comparator compound, where the expression of these particular genes were regulated in the opposite direction to the HTG compounds.

The findings and other data generated from the first library have been fed back into HTG's AI-driven discovery engine and a second generation of candidate molecules has been rendered, with a hit rate for this subsequent library of approximately 35%. Subsequent *in vitro* efficacy studies on this second generation of molecules have also demonstrated further improvement in efficacy in cell-based test system models.

The lead molecules for this second library are currently progressing through the remaining portion of lead optimization and HTG expects to have sufficient data to support entry of these lead candidate molecules into development in the third quarter of 2023. The Company has estimated market opportunity for the initial oncology indication for its first drug candidate at approximately $600 million globally. Additionally, the Company believes that the target potentially has additional value in at least six or more solid tumor indications based upon initial efficacy data generated by HTG in these other cancers.

The Company views the data that it has generated in these studies as a tangible demonstration of the power of the Company's internally-built drug discovery engine. The Company has demonstrated that it can progress from target to drug candidate in approximately 12 months with this platform approach, with the added benefit of having much deeper knowledge about the biological responses in diseased cells at these earlier development stages. The Company believes this ability to enrich its understanding of the mechanism of action for the lead compounds will allow HTG to make more informed selection choices far earlier in the process, which in turn will translate into greater chances for success in development.

HTG continues to advance the capabilities of its discovery platform, including the use of transcriptomic signatures representative of cellular perturbation from pharmacologic target modulation as a starting point where the AI system can design molecules, thus creating a capability for two way "conversations" between chemistry and biology. The Company believes this further increases the utility of its discovery platform for not only selecting and designing new molecules, but also as a key tool in potentially repurposing other drugs.

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 regarding HTG’s objectives and ability to develop best-in-class molecules; the ability of HTG’s platform to enable improved selection and design of molecules; HTG’s expectations to have sufficient data to support entry of its lead candidate molecules into development in the third quarter of 2023; the estimated market opportunity for the initial oncology indication for HTG’s first drug candidate and the potential for other solid tumor indications for the same target; the potential of HTG’s AI-driven drug discovery engine; HTG’s ability to progress from target to drug candidate using its platform approach in approximately 12 months; the ability of HTG’s platform to potentially repurpose other drugs; HTG’s expected pipeline advancement; and the capabilities of HTG’s technology. Words such as “designed to,” “believe,” “anticipate,” “expect,” “potential,” “will” 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. In addition, statements that “HTG believes” and similar statements reflect HTG’s beliefs and opinions on the relevant subject. These statements are based upon information available to the Company as of the date of this report, and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and the Company’s statements should not be read to indicate that the Company has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements contained in this report as a result of various risks and uncertainties, including risks associated with drug discovery and development; the risk that the Company’s technologies may not provide the benefits that the Company expects; risks associated with the Company’s ability to develop and commercialize its products; observations in cell-based test system models and in vitro efficacy results may not be replicated in trials in humans; risks associated with the Company’s ability to enter into licensing, partnering or other transactions for any candidates the Company discovers or develops; the risk that the Company’s products and services may not be adopted by biopharmaceutical companies or other customers as anticipated, or at all; and risks related to the Company’s need for additional capital. These and other factors are described in greater detail in the Company’s filings with the Securities and Exchange Commission (SEC), including under the “Risk Factors” heading of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on May 10, 2023. All forward-looking statements contained in this report speak only as of the date on which they were made, and the Company undertakes 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.

HTG Molecular Diagnostics, Inc.

Dated: May 16, 2023

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