
**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

April 25, 2023
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

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.

Update on Drug Discovery Partnering Initiative

HTG Molecular Diagnostics, Inc. (the “Company” or “HTG”) has pioneered a proprietary platform-based approach that is designed to help improve drug discovery, referred to as transcriptome-informed drug discovery and design. At the center of this approach is the application of HTG’s proprietary RNA profiling technologies, functionally married with advanced medicinal chemistry using a novel artificial intelligence (“AI”)-based platform. This unique drug candidate optimization platform is expected to allow for more biologically-relevant insight into drug candidate selection and design much earlier in the discovery process than in traditional drug discovery. HTG believes this approach will result in higher efficiency, improved risk management and cost efficiencies to bring novel drug candidate molecules from very early discovery through entry to development.

While the Company is still early in its partnering discussions, the Company is pleased with the level of preliminary interest in its drug discovery platform from certain pharmaceutical companies that historically in-license candidates for preclinical development as part of their business model. The Company believes this interest is driven by HTG’s highly differentiated approach to drug discovery – namely, the use of its proprietary transcriptomic profiling technologies, integrated with a machine learning-based chemical library design platform, to better-inform the design and selection of drug candidate molecules. This approach is expected to yield drug candidates with lower risk profiles and increased opportunities for development success, all while being faster and more cost-efficient than traditional approaches.

HTG looks forward to engaging with pharmaceutical companies globally to identify the best partners to carry forward the development of the Company’s early portfolio of candidate molecules in oncology and neurodegenerative disease indications, as well as with pharmaceutical companies interested in using HTG’s drug discovery engine with their own targets and libraries.

Using its advanced transcriptomic profiling platform in conjunction with an AI-driven drug discovery engine, the Company has designed two generations of molecules that have demonstrated in vitro efficacy in model systems, both as a standalone therapy and in combination with the current standard of care. The most advanced discovery molecules are progressing through lead optimization studies and the Company expects that these efforts will support entry into preclinical development in the next several months.

Achievement of First Quarter Drug Discovery Business Milestones

As previously announced, HTG achieved three significant drug discovery business milestones in the first quarter of 2023.

HTG filed a patent application on December 28, 2022, which included claims directed toward specific compounds, pharmaceutical compositions and methods of treating or preventing disease by administration of the compounds for its first target and indication. These compounds were designed by the Company’s advanced machine-learning medicinal chemistry platform using a target-first approach. That work was followed up with the first of the key first quarter 2023 milestones - in vitro demonstration of efficacy of the lead compounds both as a standalone therapy and in combination with the current standard of care. HTG considers this result a powerful demonstration of its medicinal chemistry platform.

The second key milestone achieved during the first quarter was the use of the Company’s proprietary HTG EdgeSeq RNA profiling platform to biologically interrogate the lead molecules. This data, along with other primary and secondary data, was then introduced into the Company’s AI-driven drug discovery engine, resulting in the creation of a second generation of molecules. The second generation of molecules has been subjected to the same in vitro experiments as the first, demonstrating improved efficacy over the first generation of molecules. These results also demonstrate the utility of the AI-driven drug discovery engine in combination with high-quality full transcriptome data.

The third milestone achieved was the use of the Company’s AI-driven drug discovery engine to design compounds using transcriptomic data as the starting point. These system-designed compounds showed highly similar characteristics to HTG’s lead compounds that were designed starting with the target. These results demonstrate the ability of HTG’s engine to design novel compounds based on transcriptomic data alone, which the Company believes will open other applications of this platform, including drug repurposing.

In addition to further advancing the Company’s drug discovery platform, these first quarter efforts have significantly advanced candidate molecules through lead optimization for HTG’s first oncology indication in liquid tumors, with a program in solid tumors expected to follow closely behind. This second target for the treatment of solid tumors has been selected and added to HTG’s oncology portfolio, which also includes an early pipeline in neurodegenerative diseases.

The Company made significant progress in the advancement of candidate molecules for its first target during the first quarter of 2023, using profiling study results to inform the selection and design of drug candidates, while further building its existing pipeline with additional oncology indications and neurodegenerative. The Company also further advanced its drug discovery engine, enabling HTG to not only select molecules but to design them. The Company constructed its engine in a manner that allows future scalability and flexibility for integrating multiple data streams, which the Company believes gives it the ability to continue to evolve its discovery platform going forward.

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 the expected benefits of HTG’s drug discovery platform, including the ability of the platform to better-inform the design and selection of drug candidate molecules with lower risk profiles and increased opportunities for development success, all while being faster and more cost-efficient than traditional approaches; HTG’s expectation of progressing through lead optimization studies and entering into preclinical development for HTG’s most advanced discovery molecules in the next several months; HTG’s plan to identify partners to carry forward the development of the Company’s early portfolio of candidate molecules in oncology and neurodegenerative disease indications, as well as with pharmaceutical companies interested in using HTG’s drug discovery engine with their own targets and libraries; the potential of HTG’s AI-driven drug discovery engine; the ability of HTG’s engine to design novel compounds based on transcriptomic data and its belief that doing so will open other applications of the platform (including drug repurposing); HTG’s expected pipeline advancement; expected future scalability and flexibility in HTG’s platform; 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. 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 risks associated with the Company’s ability to enter into licensing, partnering or other transactions for programs or candidates arising from the Company’s drug discovery platform, which transactions may not occur when anticipated, or at all; the risk that the Company’s drug discovery approach may not result in the selection or development of a drug candidate; various 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 the Company’s products; 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 the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 30, 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: April 25, 2023

By: /s/ Shaun D. McMeans

Shaun D. McMeans

SVP and Chief Financial Officer
