

**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 10, 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
<b>Common Stock, \$0.001 par value per share</b>	<b>HTGM</b>	<b>The Nasdaq Stock Market LLC</b>

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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 10, 2023, HTG Molecular Diagnostics, Inc. issued a press release announcing its financial results as of and for the quarter ended March 31, 2023. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the attached exhibit 99.1 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 (the “Securities Act”), or the Exchange Act.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of HTG Molecular Diagnostics, Inc. dated May 10, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**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 10, 2023

By: /s/ Shaun D. McMeans

Shaun D. McMeans

SVP and Chief Financial Officer

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FOR IMMEDIATE RELEASE

## HTG Molecular Diagnostics Reports First Quarter 2023 Results and Provides Recent Business Highlights

**TUCSON, Ariz., May 10, 2023** -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a platform-based life science tools and drug discovery company, today reported financial results for the quarter ended March 31, 2023 and provided recent drug discovery business highlights.

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")-driven 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.

HTG achieved three significant drug discovery business milestones in the first quarter of 2023 to advance the compounds for its first target and indication through lead optimization and to further strengthen its AI-driven drug discovery engine.

First, HTG achieved in vitro demonstration of efficacy of its first lead compounds both as a standalone therapy and in combination with the current standard of care.

The Company utilized its 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.

Finally, the Company's AI-driven drug discovery engine was used 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 provide other opportunities for expanded platform applications, including drug repurposing.

In addition to further advancing the Company's drug discovery platform, these first quarter efforts have significantly advanced HTG's first oncology indication in liquid tumors through lead optimization studies and the Company expects that these efforts will support entry into preclinical development in the next several months. In addition, the Company's 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.

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“Through the diligent efforts of our strong and knowledgeable team, we have once again achieved extensive progress toward our strategy to establish our transcriptome-informed drug discovery process as the preferred methodology for small molecule drug discovery, complementing and expanding the advanced capabilities that our HTG EdgeSeq technology has provided for many years in profiling. The three major milestones reached by our team during the first quarter of 2023 have not only advanced and strengthened our AI-driven drug discovery engine, but have significantly advanced candidate molecules through lead optimization for our first indication in liquid tumors, with a program in solid tumors expected to follow closely behind,” said John Lubniewski, Chief Executive Officer and Director at HTG.

Partnering discussions have been initiated with global biopharmaceutical companies around the Company's portfolio of drug candidate molecules in oncology and neurodegenerative disease indications. In addition, HTG has initiated partnering conversations regarding the use of HTG's drug discovery engine within the partners' portfolios of drug assets.

“While our partnering discussions are in early stages, we are pleased with the level of preliminary interest we have seen in our drug discovery platform from pharmaceutical companies that historically in-license candidates for preclinical development as part of their business model as well as those interested in using our AI-driven drug discovery engine with their own target portfolios,” Mr. Lubniewski continued. “We believe this interest is driven by our highly differentiated approach to drug discovery, which uses our 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. We believe that this approach will yield drug candidates with lower risk profiles and increased opportunities for development success, providing faster and more cost-efficient outcomes than traditional approaches, and believe that these potential partners are beginning to quickly understand these advantages.”

#### **First Quarter 2023 Financial Results:**

Product and product-related services revenue for the quarter ended March 31, 2023 was \$1.0 million, compared to \$1.2 million for the same period in 2022. This revenue continues to primarily reflect sales of the Company's two whole transcriptome products, the HTG Transcriptome and HTG EdgeSeq miRNA panels, to new and existing customers as consumables and sample processing services. Sales of these products represented 66% of revenue for the quarter ended March 31, 2023.

Net loss from operations for the quarter ended March 31, 2023 was \$5.0 million, compared to \$6.3 million for the same period in 2022. Net loss per share was \$(2.28) for the quarter ended March 31, 2023 compared with \$(9.73) for the first quarter of 2022, reflecting approximately 1.3 million additional common shares issued in December 2022. This operating margin improvement also reflects cost reduction measures implemented in the second quarter of 2022 which aligned the Company's profiling cost structure with expected future revenue to reduce operating cash burn.

Cash, cash equivalents and investments in available-for-sale securities totaled \$6.6 million as of March 31, 2023, with current liabilities of approximately \$6.6 million and non-current liabilities of \$3.8 million.

#### **About HTG:**

HTG is accelerating precision medicine from diagnosis to treatment by harnessing the power of transcriptome-wide profiling to drive translational research, novel therapeutics and clinical diagnostics across a variety of disease areas.

Building on more than a decade of pioneering innovation and partnerships with biopharma leaders and major academic institutes, HTG's proprietary RNA platform technologies are designed to make the development of life science tools and diagnostics more effective and efficient and to unlock a differentiated and disruptive approach to transformative drug discovery. For more information visit [www.htgmolecular.com](http://www.htgmolecular.com).

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**Forward-Looking Statements:**

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 the expected benefits of our 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; our expectation of progressing through lead optimization studies and entering into preclinical development for HTG’s most advanced discovery molecules in the next several months; our 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; and the capabilities of our 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 our ability to enter into licensing, partnering or other transactions for programs or candidates arising from our drug discovery platform, which transactions may not occur when anticipated, or at all; the risk that our 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 our technologies may not provide the benefits that we expect; risks associated with our ability to develop and 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; and risks related to our need for additional capital. These and other factors are described in greater detail in our filings with the Securities and Exchange Commission (SEC), including under the “Risk Factors” heading in our 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 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.

**HTG Investor Contact:**

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-Financial tables follow-

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

	<b>Three Months Ended March 31,</b>	
	2023	2022
Product and product-related services revenue	\$ 1,032,510	\$ 1,184,454
<b>Operating expenses:</b>		
Cost of product and product-related services revenue	1,149,608	855,048
Selling, general and administrative	3,282,948	4,663,011
Research and development	1,612,553	1,920,430
<b>Total operating expenses</b>	<b>6,045,109</b>	<b>7,438,489</b>
Operating loss	(5,012,599)	(6,254,035)
Other income (expense)	(39,955)	(243,098)
Net loss before income taxes	(5,052,554)	(6,497,133)
Provision for income taxes	(2,218)	(386)
<b>Net loss</b>	<b>\$ (5,054,772)</b>	<b>\$ (6,497,519)</b>
Net loss per share, basic and diluted	\$ (2.28)	\$ (9.73)
Shares used in computing net loss per share, basic and diluted	2,214,082	667,647



**HTG Molecular Diagnostics, Inc.**  
**Condensed Consolidated Balance Sheets**

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 2,996,409	\$ 12,210,857
Investments available-for-sale, at fair value	3,566,628	—
Accounts receivable	1,131,980	1,421,695
Inventory, net	654,917	909,328
Prepaid expenses and other	837,170	1,109,571
Total current assets	9,187,104	15,651,451
Operating lease right-of-use assets	892,685	1,007,202
Property and equipment, net	528,527	598,006
Other non-current assets	257,312	520,996
Total assets	<u>\$ 10,865,628</u>	<u>\$ 17,777,655</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,097,538	\$ 1,157,449
Accrued liabilities	1,321,771	2,209,606
SVB Term Loan, net of discount and debt issuance costs	3,075,506	3,812,498
NuvoGen obligation - current	446,031	446,031
Operating lease liabilities - current	481,967	475,126
Other current liabilities	136,074	170,047
Total current liabilities	6,558,887	8,270,757
NuvoGen obligation - non-current, net of discount	3,370,279	3,519,058
Operating lease liabilities - non-current, net of discount	423,237	546,324
Other non-current liabilities	38,723	49,819
Total liabilities	10,391,126	12,385,958
Commitments and Contingencies		
Total stockholders' equity	474,502	5,391,697
Total liabilities and stockholders' equity	<u>\$ 10,865,628</u>	<u>\$ 17,777,655</u>

