

MDxHealth Reports Financial Year 2022 Results and Provides Business Update and Outlook for 2023

Conference call with Q&A today at 4:30 PM EST / 22:30 CET

IRVINE, CA, and HERSTAL, BELGIUM – March 8, 2023 – MDxHealth SA (NASDAQ/Euronext Brussels: MDXH) (the "Company" or "mdxhealth"), a commercial-stage precision diagnostics company, today announced its financial results for the fourth quarter and year ended December 31, 2022, and provided a business update and outlook for 2023.

Highlights for the fourth quarter and year ended December 31, 2022

- Acquired Genomic Prostate Score (GPS) test (formerly Oncotype DX GPS) from Exact Sciences in August 2022, solidifying leadership in the precision diagnostics urology market and providing the most comprehensive menu of advanced molecular tests for prostate cancer in urology
- The newly released [NCCN for Prostate Cancer Guideline \(Version 1.2023\)](#)* expands the indication for use of the GPS test to include high-risk patients with localized prostate cancer. This expanded criteria acknowledges the clinical utility of GPS and enables mdxhealth to more fully serve its targeted patient population
- Revenues for the fourth quarter ended December 31, 2022, increased by 114% to \$12.9 million versus \$6.0 million for the same period last year; excluding GPS, Q4-2022 revenue increased 15% to \$6.9 million versus Q4-2021
- 2022 full year revenues increased by 67% to \$37.1 million versus \$22.2 million for 2021; excluding GPS, 2022 revenue increased 25% to \$27.7 million versus 2021
- 2022 revenues were comprised of \$21.8 million from Confirm mdx, \$9.3 million from GPS, \$4.9 million from Resolve mdx, with the remaining revenues from Select mdx and other
- Billable test volume for the fourth quarter ended December 31, 2022, for Confirm mdx increased by 21% to 4,339 versus 3,598, and for Select mdx, decreased by 6% to 3,129 versus 3,346, for the same period last year

Michael K. McGarrity, CEO of mdxhealth, commented: “We are excited to report operating results which reflect the early impact of our focused strategy of delivering multiple drivers of growth. Core to our approach are test-menu augmentation, and a newly expanded sales channel to enable cross-selling of complementary solutions which address the most important prostate cancer diagnostic questions facing urologists and patients.

“We expect our menu of Confirm mdx and Select mdx (with its anticipated Medicare coverage), coupled with the addition of our GPS and Resolve mdx tests, to increase our revenues, improve our gross margins, and drive sustainable growth in the near and long term.”

Financial review for the year ended December 31, 2022

USD in thousands (except per share data) Unaudited	Year Ended December 31		
	2022	2021	% Change
Services	36,965	21,937	69%
Licenses and royalties	89	302	(71%)
Total Revenue	37,054	22,239	67%
Cost of goods	(17,835)	(11,675)	53%
Gross Profit	19,219	10,564	82%
Operating expenses	(57,119)	(37,405)	53%
Operating loss	(37,900)	(26,841)	41%
Net loss	(44,044)	(29,002)	52%
Basic and diluted loss per share	(0.28)	(0.24)	17%

Total revenue for 2022 was \$37.1 million, an increase of 67% as compared to total revenue of \$22.2 million for 2021. Excluding revenues from the recently acquired Genomic Prostate Score (GPS) test (formerly Oncotype DX GPS), total revenue for 2022 was \$27.7 million, an increase of 25% versus 2021. 2022 revenues were comprised of \$21.8 million from Confirm mdx, \$9.3 million from GPS, \$4.9 million from Resolve mdx, with the remaining revenues from Select mdx and other.

Gross profit for 2022 was \$19.2 million as compared to \$10.6 million for 2021. Gross margins were 51.9% for 2022 as compared to 47.5% for 2021, representing a gross margin improvement of 440 basis points, primarily related to our product mix and the addition of GPS to our product menu.

Operating expenses for 2022 were \$57.1 million, up 53% from \$37.4 million for 2021, primarily related to the additional field sales personnel associated with the GPS business as well as non-recurring transaction-related expenses of \$3.2 million. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation as well as as well as the non-recurring transaction-related expenses of \$3.2 million, operating expenses for 2022 were \$48.1 million, an increase of 45% over 2021.

Operating loss and net loss for 2022 were \$37.9 million and \$44.0 million, respectively, an increase of 41% and 52%, respectively, over 2021. In addition to the reasons stated above, net loss also included a one-time financial expense of approximately \$1.2 million related to replacing the Company's debt facility.

Cash and cash equivalents as of December 31, 2022 were \$15.5 million. Total cash collections amounted to \$32.3 million during 2022, an increase of 50% compared to 2021; excluding collections from GPS, total cash collections in 2022 increase by 20% versus 2021.

Business Update and Outlook for 2023

In February 2023, the Company strengthened its balance sheet with gross proceeds of \$40 million from an equity offering consisting of 10 million American Depository Shares (ADSs). Following the underwriters' exercise of their overallotment option, the Company received an additional \$3 million of gross proceeds in March 2023, on the same terms and conditions. Including the Company's 2022 yearend cash balance of \$15.5 million, and taking into account aggregate net proceeds of \$40.4 million from this equity financing, the Company's pro-forma cash balance was \$55.9 million.

In addition, in February 2023, the Company announced that UnitedHealthcare will cover the mdxhealth Genomic Prostate Score (GPS) test to assist with treatment decisions for individuals newly diagnosed with localized prostate cancer and meeting coverage criteria. In its technical assessment of competitive tests, UnitedHealthcare's updated [Medical Policy](#) states that "the body of evidence consistently favors use of the GPS assay to assist with management strategies..." UnitedHealthcare's coverage of GPS adds to positive coverage decisions by other national and regional commercial payers, as well as from Medicare and Medicare Advantage plans.

Finally, the Company is maintaining its previously-issued 2023 revenue guidance of \$65-\$70 million.

Conference Call

Michael K. McGarrity, Chief Executive Officer and Ron Kalfus, Chief Financial Officer, will host a conference call and Q&A session today at 4:30 PM EST / 22:30 CET. The call will be conducted in English and a replay will be available for 30 days.

To participate in the conference call, please select your phone number below:

United States: 1-877-407-9716

United Kingdom: 0800 756 3429

Belgium: 0800 73904

The Netherlands: 0800 023 4340

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1600322&tp_key=c5695c9654

To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled start time.

2023 Reporting Calendar

- May 10, 2023: Q1-2023 business update
- May 25, 2023: Annual general shareholders' meeting
- August 23, 2023: Publication of H1-2023 results
- November 8, 2023: Q3-2023 business update

About mdxhealth

Mdxhealth is a commercial-stage precision diagnostics company that provides actionable molecular information to personalize patient diagnosis and treatment. The Company's tests are based on proprietary genomic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis and prognosis of urologic cancers and other urologic diseases. The Company's U.S. headquarters and laboratory operations are in Irvine, California, with additional laboratory operations in Plano, Texas. European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands. For more information, visit mdxhealth.com and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth

Financial statements and auditor review

The Company's statutory auditor, BDO Bedrijfsrevisoren BV, has confirmed that its audit procedures with respect to the Company's consolidated financial statements, prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, have been substantially completed, and that the procedures completed to date have not revealed any material adjustments that would have to be made to the accounting information derived from the Company's consolidated financial information that is included in this press release.

The condensed Consolidated Statement of Comprehensive Income may be found on the Company's website at www.mdxhealth.com. The full Annual Report is expected to be made available to the public via the Company's website in April 2022.

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This press release contains forward-looking statements and estimates with respect to the anticipated future performance of MDxHealth and the market in which it operates, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "potential," "expect," "will," "goal," "next," "potential," "aim," "explore," "forward," "future," and "believes" as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding the acquisition of Oncotype DX® GPS prostate cancer business from Exact Sciences including statements regarding the anticipated benefits of the acquisition; statements regarding expected future operating results; statements regarding product development efforts; and statements regarding our strategies, positioning, resources, capabilities and expectations for future events or performance. Such statements and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable but may not prove to be correct. Actual events are difficult to predict, may depend upon factors that are beyond the company's control, and may turn out to be materially different. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, product development efforts, our strategies, positioning, resources, capabilities and expectations for future events or performance. Important factors that could cause actual results, conditions and events to differ materially from those indicated in the forward-looking statements include, among others, the following: uncertainties associated with the coronavirus (COVID-19) pandemic, including its possible effects on our operations, and the demand for our products; our ability to successfully and profitably market our products; the acceptance of our products and services by healthcare providers; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; the possibility that the anticipated benefits from our business acquisitions like our acquisition of the Oncotype DX® GPS prostate cancer business will not be realized in full or at all or may take longer to realize than expected; and the amount and nature of competition for our products and services. Other important risks and uncertainties are described in the Risk Factors sections of our most recent Annual Report on Form 20-F and in our other reports filed with the Securities and Exchange Commission. MDxHealth expressly disclaims any obligation to update any such forward-looking statements in this release to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based unless required by law or regulation. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of MDxHealth in any jurisdiction. No securities of MDxHealth may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. securities laws.

NOTE: The mdxhealth logo, mdxhealth, Confirm mdx, Select mdx, Resolve mdx, Genomic Prostate Score, GPS and Monitor mdx are trademarks or registered trademarks of MDxHealth SA. The GPS test was formerly known as and is frequently referenced in guidelines, coverage policies, reimbursement decisions, manuscripts and other literature as Oncotype DX Prostate, Oncotype DX GPS, Oncotype DX Genomic Prostate Score, and Oncotype Dx Prostate Cancer Assay, among others. The Oncotype DX trademark, and all other trademarks and service marks, are the property of their respective owners.

*[NCCN Prostate Cancer Guidelines 1.2023 Discussion Update in Progress \(Nov.29, 2022\)](#)