

MDxHealth Reports Results for the Third Quarter and Nine-Month Period Ended September 30, 2023

IRVINE, CA, and HERSTAL, BELGIUM – November 8, 2023 – MDxHealth SA (NASDAQ/Euronext: MDXH), a commercial-stage precision diagnostics company, today announced its financial results for the third quarter and nine-month period ended September 30, 2023.

Michael K. McGarrity, CEO of mdxhealth, commented: "We are pleased to report strong operating results for the third quarter of 2023, which reflects our continued focus on and commitment to commercial execution and operating discipline. Looking ahead, we expect strong revenue growth, gross margin improvement and reduction in cash burn, all leading to our projected turn to operating profitability. With respect to guidance, we expect to reach the high end of our 2023 revenue guidance of \$65-70 million, and continue to believe we will turn profitable on an adjusted EBITDA basis in the first half of 2025."

Highlights for the third quarter ended September 30, 2023

- Q3-2023 revenue of \$19.3 million, representing an increase of 73% over Q3-2022; excluding GPS, Q3-2023 revenue increased 45% over Q2-2022
- Q3-2023 revenue was comprised of \$8.1 million from GPS, \$6.6 million from Confirm mdx, \$2.7 million from Resolve mdx, and \$1.9 million from Select mdx
- Q3-2023 gross margin expansion of 908 basis points to 64.9% versus Q3-2022 gross margin of 55.8%
- Q3-2023 billable test volumes: Confirm mdx increased by 15% to 4,932 versus the prior year period, Select mdx decreased by 2% to 2,938 versus the prior year period, and Resolve mdx increased by 101% to 6,742 versus the prior year period
- Cash and cash equivalents of \$32.7 million as of September 30, 2023

Financial review for the three and nine months ended September 30, 2023

USD in '000 (except per share data) Unaudited
Revenue
Cost of goods
Gross Profit
Operating expenses
Operating loss
Net loss
Basic and diluted loss per share

Three months ended September 30			
2023	2022	% Change	
19,350	11,154	73%	
(6,797)	(4,931)	38%	
12,553	6,223	102%	
(17,114)	(18,153)	(6%)	
(4,561)	(11,930)	(62%)	
(10,045)	(13,502)	(26%)	
(0.04)	(0.08)	(50%)	

Nine months ended September 30			
2023	2022	% Change	
50,795	24,163	110%	
(19,537)	(12,168)	61%	
31,258	11,995	161%	
(52,279)	(40,948)	28%	
(21,021)	(28,953)	(27%)	
(32,380)	(31,606)	2%	
(0.13)	(0.20)	(35%)	

Results for the three months ended September 30, 2023

Revenue increased 73% to \$19.3 million compared to \$11.2 million for the prior year. Excluding GPS, revenue increased 45% to \$11.3 million compared to \$7.8 million for the prior year.

Gross profit increased 102% to \$12.6 million compared to \$6.2 million for the prior year. Gross margins were 64.9% as compared to 55.8% for the prior year, an improvement of 908 basis points attributed to contribution from Select mdx reimbursement and Resolve mdx.

Operating loss decreased 62% to \$4.6 million compared to \$11.9 million for the prior year, driven by improved margins as well as a 6% reduction in operation expenses.

Net loss decreased 26% to \$10.0 million compared to \$13.5 million for the prior year, driven by the factors mentioned above, partially offset by an increase of \$3.8 million in financial expenses, of which \$3.6 million was non-cash and primarily related to the GPS contingent consideration.

Results for the nine months ended September 30, 2023

Revenue increased 110% to \$50.8 million compared to \$24.2 million for the prior year. Excluding GPS, revenue increased 38% to \$28.7 million compared to \$20.8 million for the prior year.

Gross profit increased 161% to \$31.3 million compared to \$12.0 million for the prior year. Gross margins were 61.5% as compared to 49.6% for the prior year, an improvement of 1,190 basis points.

Operating loss decreased 27% to \$21.0 million compared to \$29.0 million for the prior year, driven by improved margins, partially offset by an increase in operating expenses related to the additional field sales personnel associated with the GPS acquisition.

Net loss increased 2% to \$32.4 million compared to \$31.6 million for the prior year, driven by the factors mentioned above as well as an increase of \$8.6 million in financial expenses, of which \$6.8 million was non-cash and primarily related to the GPS contingent consideration, with the remainder primarily related to increased interest expense.

Cash and cash equivalents as of September 30, 2023, were \$32.7 million.

Transition to Sole Listing of Shares on NASDAQ

An extraordinary general shareholders' meeting of the Company held on November 3, 2023, approved the proposed transition from a dual listing of the Company's American Depositary Shares on Nasdaq and ordinary shares (the "Shares") on Euronext Brussels to a sole listing of Shares on Nasdaq (the "Transaction"), as well as the share consolidation with respect to all outstanding Shares by means of a 1-for-10 reverse stock split (the "Share Consolidation"). As a result, the Company can now start implementing the Transaction and Share Consolidation, as further outlined in the press release issued by the Company on November 6, 2023.

Earnout payment to Exact Sciences

On August 23, 2023, mdxhealth and Exact Sciences Corporation amended their existing Oncotype DX GPS prostate cancer business asset purchase agreement, deferring mdxhealth's initial earnout payment by 3 years, from 2024 to 2027, in consideration for an amendment fee of \$250,000 in cash and 250,000 of the Company's ADSs, a 5-year subscription right (warrant) to acquire up to 1,000,000 of the Company's ADSs at an exercise price of \$5.265 per ADS (representing a 50% premium to the market price of the ADSs as of August 18, 2023), and an increase in the potential aggregate earnout amount from \$70 million to \$82.5 million. The Company agreed to convene a general shareholders' meeting to approve the subscription right. Under the terms of the amended asset purchase agreement, mdxhealth has agreed to make earn-out payments to Exact Sciences in each of fiscal years 2025, 2026 and 2027, based upon certain revenues related to fiscal years 2024, 2025 and 2023, respectively. At the option of mdxhealth, the earn-out amounts can be settled in cash or through the issuance of additional ADSs or Shares of the Company (valued as a function of the volume weighted average trading price of the Company's Shares at the end of the relevant earnout period) to Exact Sciences, provided that the aggregate number of shares held by Exact Sciences shall not exceed more than 7.5% (increased from 5% in the initial agreement) of the outstanding shares of mdxhealth.

Coverage Expansion

On August 9, 2023, mdxhealth announced that Cigna, one of the largest health insurers in the United States, expanded commercial and Medicare Advantage coverage to include the Company's Select mdx for Prostate Cancer test. With the addition of Select mdx, Cigna will now provide insurance coverage across mdxhealth's full menu of precision diagnostic cancer tests, including its Confirm mdx and GPS tests, which represent more than 15 million lives under coverage. Contracted coverage with Cigna for the Select mdx test is expected to take effect in Q4 of this year.

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: 1-888-886-7786

Belgium: 0800 76018

The Netherlands: 0800 022 7908 United Kingdom: 4480 065 22435

Conference ID: 00680078

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1636749&tp_key=4b4cf524b1

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

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

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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 expected future operating results; expectations for development of new or improved products and services and their impact on patients; our strategies, positioning, resources, capabilities and expectations for future events or performance; and the anticipated benefits of our acquisitions, including estimated synergies and other financial impacts. 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; our ability to achieve and maintain adequate levels of coverage or reimbursement for our current and future solutions we commercialize or may seek to commercialize; 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; timing, progress and results of our research and development programs; the period over which we estimate our existing cash will be sufficient to fund our future operating expenses and capital expenditure requirements; 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.