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Mdxhealth Announces Fourth Quarter and Full-Year 2023 Financial Results

2023 revenue grew by 89% to \$70.2 million; excluding GPS, revenues up 42% 2023 gross margin expanded by 10.7 percentage points over prior year Conference call with Q&A today at 4:30 PM EST / 22:30 CET

IRVINE, CA, and HERSTAL, BELGIUM – March 6, 2024 (<u>GlobeNewswire</u>) – MDxHealth SA (NASDAQ: 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, 2023.

Michael K. McGarrity, CEO of mdxhealth, commented: "Our fourth quarter and full year 2023 results reflect our continued commitment to commercial execution and operational discipline that has driven significant gross margin expansion across our business. With each passing quarter, we continue to build on our position as a leading precision diagnostics company rooted in our industry-leading technology, focus on the highest quality customer experience, and our unwavering commitment towards improving patient outcomes. We remain well positioned to build upon this success as we actively evaluate multiple, high-growth opportunities that could further strengthen and complement our existing menu. In 2024, we expect to deliver continued topline growth and operating execution that will lead to adjusted EBITDA profitability in the first half of 2025."

Key Highlights:

- Completed transition to sole listing of its shares on NASDAQ
- Secured Medicare coverage for the Company's Select mdx test
- Fourth quarter revenue of \$19.4 million, an increase of 50% over prior year period
- 2023 revenue of \$70.2 million, an increase of 89% or 42% excluding GPS

Financial review for the fourth quarter and year ended December 31, 2023

USD in '000 (except per share data)	Three months ended December 31				Twelve months ended December 31			
Unaudited	2023	2022	% Change		2023	2022	% Change	
Revenue	19,398	12,891	50%		70,193	37,054	89%	
Cost of goods	(6,727)	(5 <i>,</i> 667)	19%		(26,264)	(17,835)	47%	
Gross Profit	12,671	7,224	75%		43,929	19,219	129%	
Operating expenses	(18,977)	(16,171)	17%		(71,256)	(57,119)	25%	
Operating loss	(6,306)	(8,947)	(30%)		(27,327)	(37,900)	(28%)	
Net loss	(10,720)	(12,438)	(14%)		(43,100)	(44,044)	(2%)	
Basic and diluted loss per share	(0.39)	(0.76)	(48%)		(1.66)	(2.78)	(40%)	

Fourth Quarter 2023 Financial Results

Revenue increased 50% to \$19.4 million compared to \$12.9 million for the prior year. Revenue was comprised of \$8.8 million from GPS, \$5.9 million from Confirm mdx, \$3.2 million from Resolve mdx, and \$1.3 million from Select mdx.

Gross margins were 65.3% compared to 56.0% for the prior year, an improvement of 9.3 percentage points attributed to contribution from Select mdx reimbursement, coupled with cost management and expanded coverage across our menu.

Operating expenses increased 17% to \$19.0 million compared to \$16.2 million for the prior year, driven by increases in R&D expense, increased sales and marketing activity from the GPS acquisition, as well as \$1.7 million of non-recurring expenses, primarily attributed to the transition to a sole listing on NASDAQ.

Net loss decreased 14% to \$10.7 million compared to \$12.4 million for the prior year, driven by the factors mentioned above, partially offset by an increase of \$2.1 million in financial expenses, of which \$1.8 million was non-cash.

Full Year 2023 Financial Results

Revenue increased 89% to \$70.2 million compared to \$37.1 million for the prior year. Excluding GPS, revenue increased 42% to \$39.3 million compared to \$27.7 million for the prior year. Revenue was comprised of \$30.9 million from GPS, \$24.8 million from Confirm mdx, \$9.7 million from Resolve mdx, and \$4.5 million from Select mdx.

Gross margins were 62.6% compared to 51.9% for the prior year, an improvement of 10.7 percentage points attributed to contribution from Select mdx reimbursement, cost management, expanded coverage across our menu, and a higher contribution from GPS to total revenue.

Operating expenses increased 25% to \$71.3 million compared to \$57.1 million for the prior year, primarily driven by the acquisition of the GPS test in August 2022, and includes \$2.6 million of non-recurring expenses, primarily attributed to the transition to a sole listing on NASDAQ.

Net loss decreased 2% to \$43.1 million compared to \$44.0 million for the prior year, driven by the factors mentioned above, partially offset by an increase of \$11.4 million in financial expenses, of which \$9.1 million was non-cash and primarily related to the GPS contingent consideration.

Cash and cash equivalents as of December 31, 2023, were \$22.4 million.

Business Update and Outlook for 2024

The Company is maintaining its previously issued 2024 revenue guidance of \$79-81 million and confirms its view of expected adjusted EBITDA profitability in the first half of 2025.

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: 1-800-652-2435 Webcast: <u>https://viavid.webcasts.com/starthere.jsp?ei=1655339&tp_key=a93e4440eb</u>

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. 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: 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.

Non-IFRS Measures. The Company's reference to adjusted EBITDA is a forward-looking statement about the Company's future financial performance, and is a non-IFRS measure that excludes a number of expense items that are included in net loss, including adjustments for items like stock-based compensation, acquisition and integration costs, impairment of long-lived assets, fair-value adjustment, loan extinguishment costs, as well as other non-operating, non-recurring expenses that are difficult to predict for future periods because the nature of the adjustments pertain to events that have not yet occurred. As a result, positive adjusted EBITDA may be achieved while a significant net loss persists. Non-IFRS financial information has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with IFRS, and such information is referenced for supplemental information purposes only. Management does not forecast many of the excluded items for internal use, as these are difficult to predict for future periods because is therefore not available without unreasonable effort, and is not provided. The occurrence, timing, and amount of any of the items excluded from IFRS to calculate non-IFRS measures could significantly impact the Company's IFRS results.

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.

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UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

	Three Months Ended December 31,			Year Ended December 31,				
In thousands of \$ (except per share amounts)	2023		2022		2023			2022
Revenues Cost of goods & services sold Gross profit Research and development expenses Selling and marketing expenses General and administrative expenses Amortization of intangible assets	\$	19,398 (6,727) 12,671 (1,829) (9,484) (6,730) (1,127)	\$	12,891 (5,667) 7,224 (799) (8,467) (5,746) (1,559)	\$	70,193 (26,264) 43,929 (6,376) (36,915) (23,010) (4,494)	\$	37,054 (17,835) 19,219 (5,497) (25,704) (23,308) (3,169)
Other operating (expense) income, net		193		400		(461)		559
Operating loss Financial expenses, net Loss before income tax Income tax		(6,306) (4,413) (10,719) (1)		(8,947) (3,363) (12,310) (128)		(27,327) (15,772) (43,099) (1)		(37,900) (6,144) (44,044) 0
Loss for the period	\$	(10,720)	\$	(12,438)	\$	(43,100)	\$	(44,044)
Loss per share attributable to parent Basic and diluted	\$	(0.39)	\$	(0.76)	\$	(1.66)	\$	(2.78)

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

In thousands of \$	December 31, 2023			December 31, 2022		
ASSETS						
Non-current assets						
Goodwill	\$	35,926	\$	35,926		
Intangible assets		44,337		46,166		
Property, plant and equipment		4,956		3,791		
Right-of-use assets		4,989		4,103		
Financial assets		763		-		
Total non-current assets		90,971		89,986		
Current assets						
Inventories		2,779		2,327		
Trade receivables		11,088		9,357		
Prepaid expenses and other current assets		1,914		1,962		
Cash and cash equivalents		22,380		15,503		
Total current assets		38,161		29,149		
TOTAL ASSETS	\$	129,132	\$	119,135		
EQUITY						
Share capital	\$	173,931	\$	133,454		
Issuance premium		153,177		153,177		
Accumulated deficit		(331,446)		(288,346)		
Share-based compensation		12,139		11,474		
Translation reserve		(593)		(444)		
Total equity		7,208		9,315		
LIABILITIES						
Non-current liabilities						
Loans and borrowings		35,564		34,914		
Lease liabilities		3,578		3,091		
Other non-current financial liabilities		63,259		53,537		
Total non-current liabilities		102,401		91,542		
Current liabilities						
Loans and borrowings		643		616		
Lease liabilities		1,480		1,172		
Trade payables		8,811		10,178		
Other current liabilities		5,694		3,985		
Other current financial liabilities		2,895		2,327		
Total current liabilities		19,523		18,278		
Total liabilities		121,924		109,820		
TOTAL EQUITY AND LIABILITIES	\$	129,132	\$	119,135		

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

	Year Ended December 31,					
In thousands of \$	 2023	2022				
CASH FLOWS FROM OPERATING ACTIVITIES						
Operating loss	\$ (27,327) \$	(37,900)				
Depreciation and amortization	6,859	4,909				
Impairment	-	44				
Share-based compensation	665	867				
Other non-cash transactions	421	(473)				
Cash used in operations before working capital changes	(19,382)	(32,553)				
Increase (-) in inventories	(452)	(416)				
Increase (-) in receivables	(1,683)	(5,122)				
Increase (+) in payables	20	3,973				
Net cash outflow from operating activities	 (21,497)	(34,118)				
CASH FLOWS FROM INVESTING ACTIVITIES						
Purchase of property, plant and equipment	(2,747)	(2,789)				
Acquisition and generation of intangible assets	(2,272)	(1,374)				
Acquisition of Genomic Prostate Score Business	-	(25,000)				
Interests received	1,088	125				
Net cash outflow from investing activities	 (3,931)	(29,038)				
CASH FLOWS FROM FINANCING ACTIVITIES						
Proceeds from issuance of shares, net of transaction costs	39,599	-				
Proceeds from loan obligation	-	34,291				
Repayment of loan obligation and debt extinguishment costs	(1,659)	(10,805)				
Amendment fee related to GPS asset purchase agreement	(250)	-				
Payment of lease liability	(1,610)	(1,358)				
Payment of interest	(3,610)	(1,412)				
Other financial expenses	 (190)	-				
Net cash inflow from financing activities	32,280	20,716				
Net increase (+) / decrease (-) in cash and cash equivalents	6,852	(42,440)				
Cash and cash equivalents at beginning of the financial year	15,503	58,498				
Effect on exchange rate changes	 25	(555)				
Cash and cash equivalents at end of the financial year	\$ 22,380 \$	15,503				