

MDxHealth Reports Results for the Third Quarter and Nine-Month Period Ended September 30, 2024

Tissue-based test volumes increase by 36%, liquid-based test volumes by 24%

Company raises 2024 revenue guidance to \$87-89 million, representing 25% growth

Pro-forma cash of \$53.5 million

Conference call and webcast today at 4:30pm ET

IRVINE, CA – November 6, 2024 ([GlobeNewswire](#)) – MDxHealth SA (NASDAQ: MDXH) (the "Company" or "mdxhealth"), a leading precision diagnostics company, today announced its financial results for the third quarter and nine-month period ended September 30, 2024.

Michael K. McGarrity, CEO of mdxhealth, commented: “We generated another strong topline performance in the third quarter of 2024, with year-over-year revenue growth of 21%, or 27% when adjusted for a backlog of Select mdx revenues in Q3 of last year following the finalization of Medicare coverage. Demand for our comprehensive menu remains robust, and we have commercial and market access teams in place to drive sustainable growth. We also strengthened our balance sheet during the quarter, with participation from existing and new investors, which enables us to drive continued growth and deliver on our view of turning adjusted EBITDA positive in the first half of next year.

“Based on our expectation of continued execution, we are taking our 2024 revenue guidance up from \$85-87 million to \$87-89 million, representing 25% year-over-year revenue growth at the midpoint of our guidance. Looking forward, based on our performance, breadth of menu, and market opportunity, we expect our 2025 revenue to meet or exceed our long-term objective of 20% sustainable growth.”

Key highlights for the third quarter:

- Revenue of \$23.3 million, an increase of 21% over prior year period, or 27% when adjusted for a one-time backlog of Select mdx revenue in Q3 of last year following the finalization of Medicare coverage
- Tissue-based (Confirm mdx and GPS) test volume of 10,767, an increase of 36% over prior year period
- Liquid-based (Select mdx, Resolve mdx, Germline) test volume of 12,028, an increase of 24% over prior year period
- Strengthened our balance sheet with gross proceeds of \$40 million through an equity offering in September 2024, or \$44 million on a pro-forma basis, adjusted for the October overallotment option detailed below
- Cash and cash equivalents as of September 30, 2024, of \$49.3 million, or \$53.5 million on a pro-forma basis, adjusted for the October overallotment.

Financial review for the three and nine months ended September 30, 2024

USD in '000 (except per share data) Unaudited	Three months ended September 30			Nine months ended September 30		
	2024	2023	% Change	2024	2023	% Change
Revenue	23,317	19,350	21%	65,310	50,795	29%
Cost of goods	(9,042)	(6,797)	33%	(25,686)	(19,537)	31%
Gross Profit	14,275	12,553	14%	39,624	31,258	27%
Operating expenses	(20,367)	(17,114)	19%	(59,738)	(52,279)	14%
Operating loss	(6,092)	(4,561)	34%	(20,114)	(21,021)	(4%)
Net loss	(11,189)	(10,045)	11%	(31,228)	(32,380)	(4%)
Basic and diluted loss per share	(0.40)	(0.37)	8%	(1.14)	(1.27)	(10%)

Results for the three months ended September 30, 2024

Revenue increased 21% to \$23.3 million compared to \$19.3 million for the prior year. Revenue in the third quarter of 2024 was comprised of 80% from tissue-based tests.

Gross profit increased 14% to \$14.3 million compared to \$12.6 million for the prior year. Gross margins were 61.2% as compared to 64.9% for the prior year, a decline of 370 basis points attributed to product mix as well as a backlog of Select mdx Medicare cases that were recognized in the third quarter of last year.

Operating loss increased 34% to \$6.1 million compared to \$4.6 million for the prior year, driven by timing of clinical study expenses, GPS laboratory transition, backlog of Select mdx revenue of approximately \$1 million in Q3 of last year, as well as sales incentive compensation associated with the unit and revenue growth.

Net loss increased 11% to \$11.2 million compared to \$10.0 million for the prior year, for the reasons stated above.

Results for the nine months ended September 30, 2024

Revenue increased 29% to \$65.3 million compared to \$50.8 million for the prior year. Revenue for the nine-month period was comprised of 80% from tissue-based tests.

Gross profit increased 27% to \$39.6 million compared to \$31.3 million for the prior year. Gross margins were 60.7% as compared to 61.5% for the prior year, a decline of 90 basis points for the same reasons noted above.

Operating loss decreased 4% to \$20.1 million compared to \$21.0 million for the prior year, driven by higher revenues.

Net loss decreased 4% to \$31.2 million compared to \$32.4 million for the prior year, primarily driven by the factors mentioned above. Net loss included one-time debt extinguishment costs of \$3.1 million as a result of refinancing the Innovatus debt with the new OrbiMed facility. Excluding the debt extinguishment costs, net loss would have been \$28.1 million, a reduction of 13% versus prior year.

Cash and cash equivalents as of September 30, 2024, were \$49.3 million, which include net proceeds of \$37.8 million from the recent financing. On October 28, 2024, the underwriters of our September offering exercised their overallotment option to purchase an additional 2,209,241 shares, providing mdxhealth with an additional \$4.2 million in net proceeds. This brings pro-forma September 30, 2024 cash balance to \$53.5 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: 1-844-825-9789

Belgium: 0800 38 961

The Netherlands: 0800 94 94 506

United Kingdom: 0808 238 9064

Conference ID: 10193602

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1692944&tp_key=8f9b7ff5cf

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. For more information, visit mdxhealth.com and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

For more information:

info@mdxhealth.com

LifeSci Advisors (IR & PR)

US: +1 949 271 9223

ir@mdxhealth.com

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; 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; our ability to remain in compliance with financial covenants made to and make scheduled payments to our creditors; 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.

CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

<i>THOUSANDS OF \$ (except per share data)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues	23,317	19,350	65,310	50,795
Cost of sales (exclusive of amortization of intangible assets)	(9,042)	(6,797)	(25,686)	(19,537)
Gross Profit	14,275	12,553	39,624	31,258
Research and development expenses	(2,697)	(1,557)	(7,764)	(4,547)
Selling and marketing expenses	(10,619)	(9,060)	(31,280)	(27,431)
General and administrative expenses	(5,735)	(5,381)	(16,936)	(16,280)
Amortization of intangible assets	(1,327)	(1,128)	(3,575)	(3,367)
Other operating income (expense), net	11	12	(183)	(654)
Operating loss	(6,092)	(4,561)	(20,114)	(21,021)
Financial income	197	564	1,772	1,570
Financial expense	(4,960)	(6,048)	(12,552)	(12,929)
Loss before income tax	(10,855)	(10,045)	(30,894)	(32,380)
Income tax	(334)	-	(334)	-
Loss for the period	(11,189)	(10,045)	(31,228)	(32,380)
Loss per share attributable to parent				
Basic and diluted	(0.40)	(0.37)	(1.14)	(1.27)

CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

<i>THOUSANDS OF \$</i>	as of September 30, 2024	as of December 31, 2023
ASSETS		
Goodwill	35,926	35,926
Intangible assets	41,924	44,337
Property, plant and equipment	4,672	4,956
Right-of-use assets	3,870	4,989
Financial assets	822	763
Non-current assets	87,214	90,971
Inventories	4,384	2,779
Trade receivables	14,993	11,088
Prepaid expenses and other current assets	1,545	1,914
Cash and cash equivalents	49,272	22,380
Current assets	70,194	38,161
Total assets	157,408	129,132
EQUITY		
Share capital	213,931	173,931
Issuance premium	149,859	153,177
Accumulated deficit	(362,674)	(331,446)
Share-based compensation	16,458	12,139
Translation reserve	(580)	(593)
Total equity	16,994	7,208
LIABILITIES		
Loans and borrowings	50,873	35,564
Lease liabilities	2,537	3,578
Other non-current financial liabilities	41,463	63,259
Non-current liabilities	94,873	102,401
Loans and borrowings	485	643
Lease liabilities	1,440	1,480
Trade payables	10,385	8,811
Other current liabilities	7,331	5,694
Other current financial liabilities	25,900	2,895
Current liabilities	45,541	19,523
Total liabilities	140,414	121,924
Total equity and liabilities	157,408	129,132

CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF CASH FLOWS

Nine Months Ended
September 30,

<i>THOUSANDS OF \$</i>	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Operating loss	(20,114)	(21,021)
Depreciation	2,271	1,910
Amortization of intangible assets	3,575	3,367
Share-based compensation	1,059	457
Other non-cash transactions	(85)	276
Cash used in operations before working capital changes	(13,294)	(15,011)
Changes in operating assets and liabilities		
Increase (-) in inventories	(1,605)	(541)
Increase (-) / decrease (+) in receivables	(3,536)	1,278
Increase (+) in payables	3,023	151
Net cash outflow from operating activities	(15,412)	(14,123)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(996)	(2,399)
Acquisition and generation of intangible assets	(971)	(1,612)
Interest received	560	756
Net cash outflow from investing activities	(1,407)	(3,255)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of shares, net of transaction costs	37,206	39,599
Proceeds from loan obligation	53,051	-
Repayment of loan obligation, loan modification, and debt extinguishment costs	(39,929)	(1,239)
Payment of lease liability	(1,409)	(1,121)
Payment of interest	(4,899)	(2,666)
Other financial expense	(306)	-
Net cash inflow from financing activities	43,714	34,573
Net increase in cash and cash equivalents	26,895	17,195
Cash and cash equivalents at beginning of the period	22,380	15,503
Effect of exchange rates	(3)	16
Cash and cash equivalents at end of the period	49,272	32,714