

MDxHealth Reports Financial Year 2021 Results and Provides Outlook and Guidance for 2022

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

IRVINE, CA, and HERSTAL, BELGIUM – March 2, 2022 – MDxHealth SA (NASDAQ/Euronext: MDXH), a commercial-stage precision diagnostics company, today announced its financial results for the fourth quarter and year ended December 31, 2021 and provided a business update and outlook for 2022.

2021 Business Highlights

- Revenues for the fourth quarter ended December 31, 2021, increased by 46% to \$6.0 million compared to the same period last year
- Revenues for full year 2021 increased by 20% to \$22.2 million compared to full year 2020
- Draft Local Coverage Determination (LCD) for Biomarkers for Prostate Cancer published by Palmetto GBA (under its MoIDx program) citing evidence of the clinical utility of SelectMDx[®]
- Strengthened balance sheet through successful initial public offering (IPO) on the NASDAQ, raising gross proceeds of \$45 million

Michael K. McGarrity, CEO of MDxHealth, commented: “While 2021 presented continued headwinds related to the pandemic and its continued effect on patient flow for our particular patient population in prostate cancer, we have made significant progress and we believe our results provide evidence that MDxHealth will emerge from this challenging period with strong and sustainable growth.

“We believe this progress is evidenced by the following:

- Publication of draft foundational Local Coverage Determination (LCD) for *Biomarkers to Stratify Patients at Increased Risk for Prostate Cancer* by Palmetto GBA under its MoIDx program, which cites evidence of the clinical utility of SelectMDx[®] and, when finalized, is expected to support coverage for qualified Medicare patients throughout the United States;
- Improvement in cash collections and capital allocation, driven by continued focus on operating discipline;
- Advancement of development programs to expand our prostate cancer menu into Active Surveillance;
- Introduction of novel Urinary Tract Infection (UTI) testing services into our urology channel which we are confident will contribute to our total revenue in 2022.”

Highlights for the fourth quarter and year ended December 31, 2021

- Revenues for the fourth quarter ended December 31, 2021, increased by 46% to \$6.0 million versus \$4.1 million for the same period last year
- 2021 revenues increased by 20% to \$22.2 million versus \$18.5 million for 2020
- Billable test volume for the fourth quarter ended December 31, 2021 for ConfirmMDx[®] decreased by 3% to 3,598 versus 3,704, and for Select decreased by 4% to 3,346 versus 3,472, for the same period last year
- 2021 billable test volume for ConfirmMDx[®] and SelectMDx increased by 3% to 15,324 and 13,615, respectively, versus 14,945 and 13,201, respectively, for 2020
- Successfully completed initial public offering (IPO) in the United States on the NASDAQ, raising gross proceeds of \$45 million
- Cash balance as of December 31, 2021 of \$58.5 million

Financial review for the year ended December 31, 2021

<i>USD in thousands (except per share data)</i> <i>Unaudited</i>	<i>Year Ended December 31</i>		
	2021	2020	% Change
Services	21,937	18,064	21%
Licenses and royalties	302	396	(24%)
Total Revenue	22,239	18,460	20%
Cost of goods	(11,675)	(10,416)	12%
Gross Profit	10,564	8,044	31%
Operating expenses	(37,405)	(35,167)	6%
Operating loss	(26,841)	(27,123)	(1%)
Net loss	(29,002)	(28,662)	1%
Basic and diluted loss per share	(0.24)	(0.34)	(30%)

Total revenue for 2021 was \$22.2 million, an increase of 20% as compared to total revenue of \$18.5 million for 2020. Services revenue amounted to \$21.9 million, an increase of 21% as compared to \$18.1 million a year earlier. Revenue from ConfirmMDx represented over 90% of services revenue for all periods.

Gross profit for 2021 was \$10.6 million as compared to \$8.0 million for 2020. Gross margins were 47.5% for 2021 as compared to 43.6% for 2020, representing a gross margin improvement of 390 basis points, primarily related to a higher average selling price (ASP).

Operating expenses for 2021 were \$37.4 million, up 6% from \$35.2 million for 2020. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation, operating expenses for 2021 were \$33.1 million, an increase of 10% over 2020, primarily driven by R&D expenses related to our future product pipeline.

Operating loss and net loss for 2021 were \$26.8 million and \$29.0 million, respectively, substantially flat compared to \$27.1 million and \$28.7 million, respectively, for 2020.

Cash and cash equivalents as of December 31, 2021 were \$58.5 million, strengthened by gross proceeds from the January equity raise of €25 million (approximately \$30 million) and the November NASDAQ IPO of \$45 million. Total cash collections amounted to \$21.5 million during 2021, an increase of 1% compared to 2020. Cash burn for 2021 was \$26.8 million compared to \$21.9 million in the prior year period.

Outlook for 2022

Michael K. McGarrity, CEO of MDxHealth, commented: “Even amidst the dynamics of the pandemic’s impact on patient visits, we anticipate a return of patient flow and continued adoption of SelectMDx and ConfirmMDx, which are emerging as the standard of care in the diagnostic pathway of patients at risk for prostate cancer. We believe that these tests will take hold and drive growth into and beyond 2022.

In addition, we are developing solutions for active surveillance (AS) of prostate cancer with our AS-MDx and Monitor-MDx tests. These menu additions would provide clinically actionable results for urologists evaluating cancer patients considered for active surveillance, as well as regular monitoring of these patients where the current standard of care is an invasive and costly annual biopsy. This is a well-characterized market where urologist are seeking a less invasive actionable solution.

We believe these initiatives, coupled with our current menu, will position MDxHealth to be the market leader in providing urologists with advanced diagnostics to support a patient from an elevated PSA through the diagnostic continuum of care with increased clinical insight and confidence.

Finally, we are encouraged by the initial introduction of novel molecular UTI testing services into our focused urology channel. The market for UTI testing is well-defined, with urologists accounting for approximately 20% of the 10 million UTI tests ordered annually in the U.S.”

Based on these catalysts for growth, MDxHealth is providing the following guidance, with growth in 2022 driven by:

- Issuance of a final LCD for the SelectMDx test, supporting additional coverage from commercial payers and contributing to both revenue and gross margin growth in the second half of 2022;
- Achieving full year 2022 revenue of \$25 million to \$27 million, representing growth of 13%-21% over full year 2021 revenue of \$22.2 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 and use the Conference ID: 2329214.

International: +1-323-994-2093

United Kingdom: 0800 358 6377

Belgium: 0800 58228

The Netherlands: 0800 023 1436

United States: +1-888-204-4368

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1529679&tp_key=255b0ee24b

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

2022 Reporting Calendar

- April 20, 2022: Q1-2022 business update
- May 25, 2022: Annual general shareholders' meeting
- August 25, 2022: Publication of H1-2022 results
- October 20, 2022: Q3-2022 business update

About MDxHealth

MDxHealth is a commercial-stage precision diagnostics company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The Company's tests are based on proprietary genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers and prognosis of recurrence risk. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and U.S. headquarters and laboratory operations based in Irvine, California. 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 as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, have been substantially completed, 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. 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; and the amount and nature of competition for our products and services. 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.

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