

MDxHealth Reports Half Year 2021 Results

Conference call with Q&A today at 19:00 CET / 1PM US ET, details provided below

IRVINE, CA, and HERSTAL, BELGIUM – August 26, 2021 – MDxHealth SA (Euronext: MDXH.BR), a commercial-stage precision diagnostics company, today announced its financial results for the half year ended June 30, 2021.

Michael K. McGarrity, CEO of MDxHealth, commented: “We are encouraged by our positive progress in the first half of 2021. Our results reflect our confidence that the key fundamentals of our business are in place and will drive sustained growth for MDxHealth.

“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 MoDx 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;
- Third consecutive quarter of sequential increases in billable volume for our ConfirmMDx[®] test, second consecutive quarter of sequential increases in billable volume for our SelectMDx[®] test;
- Improvement in collections and capital allocation, supported by continued focus on operating discipline; and
- Advancement of development programs to expand our Prostate Cancer menu into Active Surveillance.

“In addition to positive results for our menu of SelectMDx and ConfirmMDx, at the conclusion of the half year, we made a Urinary Tract Infection (UTI) diagnostic panel available to a limited number of urology practices, as our first channel opportunity into urology, where approximately 20% of the 10 million UTI patients present in the U.S. annually. As we have stated, we have restructured our sales and overall commercial team to not only drive growth of our core and expanding prostate cancer menu, but to also take advantage of additional opportunities to serve our customer base and leverage this channel.”

Highlights for the half year and quarter ended June 30, 2021

- H1-2021 services revenue of \$10.5 million, up 9% as compared to \$9.6 million in H1-2020; Q2-2021 services revenue up 43% from Q2-2020
- H1-2021 ConfirmMDx billable test volume increased 4% to 7,978 versus 7,662 for the same period last year; Q2-2021 up 30% from Q2-2020 and 4% sequentially from Q1-2021
- H1-2021 SelectMDx billable test volume increased 9% to 7,051 versus 6,462 for the same period last year; Q2-2021 up 82% from Q2-2020 and 16% sequentially from Q1-2021
- Cash balance as of June 30, 2021 was \$31.3 million; cash use in H1-2021 was \$13.1 million, an increase of \$0.2 million, or 1%, versus cash use in H1-2020
- Successful financing of €25 million (approximately \$30 million), with broad support from U.S. and European investors including continued support from our Reference shareholders, MVM, Valiance and BioVest

Summary of Billable Test Volume by Product

Product	Second Quarter Ended June 30,		
	2021	2020	% Change
ConfirmMDx	4,065	3,130	30%
SelectMDx	3,792	2,079	82%

Product	Half Year Ended June 30,		
	2021	2020	% Change
ConfirmMDx	7,978	7,662	4%
SelectMDx	7,051	6,462	9%

Financial review for the half year ended June 30, 2021

USD in thousands (except per share data) Unaudited	Half Year Ended June 30		
	2021	2020	% Change
Services	10,462	9,596	9%
Licenses and royalties	269	284	(5%)
Total Revenue	10,731	9,880	9%
Gross Profit	5,215	4,686	11%
Operating expenses	(17,658)	(17,674)	0%
Operating loss	(12,443)	(12,988)	(4%)
Net loss	(13,299)	(13,709)	(3%)
Basic and diluted loss per share	(0.12)	(0.18)	(33%)

Total revenue for the first half of 2021 was \$10.7 million compared to total revenue of \$9.9 million for the first half of 2020. Revenue from ConfirmMDx and SelectMDx amounted to \$10.5 million, an increase of 9% as compared to \$9.6 million a year earlier. Revenue from ConfirmMDx represented over 90% of product revenue for all periods.

Gross profit on products and services for the first half of 2021 was \$5.2 million as compared to \$4.7 million for the first half of 2020. Gross margins on products and services were 48.6% for the first half of 2021 as compared to 47.4% for the same period in 2020, representing a gross margin improvement of 120 basis points.

Operating expenses in the first half of 2021 were \$17.7 million, consistent with the same period last year. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation, operating expenses for H1-2021 were \$15.7 million, an increase of \$0.3 million, or 2%, over H1-2020.

Operating loss and net loss for the first half of 2021 were \$12.4 million and \$13.3 million, respectively, with losses narrowing compared to \$13.0 million and \$13.7 million, respectively, over the same period in 2020, for the reasons stated above.

Cash and cash equivalents as of June 30, 2021, were \$31.3 million, strengthened by the January 2021 equity raise of €25 million (approximately \$30 million). Total cash collections amounted to \$10.2 million in H1-2021, a decrease of 11% compared to the same period last year, due to the impact of COVID-19. Cash burn for H1-2021 was \$13.1 million compared to \$12.9 million in the prior year period.

Outlook

Michael K. McGarrity, CEO of MDxHealth, commented: “Even amidst the dynamics of the pandemic and its variant strains, as well as the impact on patient flow, we are confident that adoption of SelectMDx and ConfirmMDx as standard of care in the diagnostic pathway of patients at risk for prostate cancer is beginning to take hold and will drive long term growth beyond 2021.

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

“We believe these initiatives, coupled with our current menu, will allow MDxHealth to be uniquely positioned to provide urologists with advanced diagnostics to take a patient from an elevated PSA through the diagnostic continuum of care with clinical confidence.

“Finally, we are excited to extend our menu of precision test offerings into our direct urology channel in the U.S., with a limited introduction of a UTI test. The market for UTI testing is well-defined, with urologists accounting for approximately 20% of the 10 million UTI tests ordered annually. This market is one of the few remaining diagnostic segments that relies on outdated culture methods. A rapid and highly sensitive UTI offering can provide timely and clinically actionable results. We look forward to providing additional visibility to our progress and outlook for this channel expansion opportunity.”

Subsequent Events

Mr. Timothy Still, Independent Non-Executive Director (serving through Tstill Enterprises LLC), has stepped down from the Board of the Company on July 28, 2021 to pursue other opportunities. The Company thanks Mr. Still for his services and wishes him success in his new endeavors.

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 19:00 CET / 1PM US ET. 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: **5051964**.

International: 323-794-2093

Belgium: 0800 58228

The Netherlands: 0800 023 1436

United Kingdom: 0800 358 637

US: 800-458-4121

Webcast: <http://public.viavid.com/index.php?id=146152>

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 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 CVBA, has confirmed that its review procedures with respect to the Company's condensed consolidated financial statements as of and for the six-month period ended 30 June 2021, 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. The aforementioned condensed consolidated financial statements may be found on the Company's website at www.mdxhealth.com.

For more information:

MDxHealth

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. 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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