

MDxHealth Reports Financial Year 2020 Results and Provides Outlook for 2021

Conference call with Q&A today at 08:00 CET / 07:00 GMT, details provided below

IRVINE, CA, and HERSTAL, BELGIUM – March 3, 2021 – MDxHealth SA (Euronext: MDXH.BR), a commercial-stage innovative molecular diagnostics company, today announced its financial results for the year ended December 31, 2020 and provided a business update and outlook for 2021.

Michael K. McGarrity, CEO of MDxHealth, commented: “While 2020 has indeed presented challenges due to the COVID-19 pandemic and the impact on the market, we have made significant progress based on our commitment to execute on our stated goals of advancing our turnaround of every operating discipline within the business.

“We believe this progress is evidenced by the following:

- Infusion of \$14 million in growth capital in 2020 from funds managed by MVM Partners LLP, followed by our January 2021 successful financing of \$30 million, with broad support from U.S. and European investors including continued support from our Reference shareholders, MVM, Valiance and BioVest;
- SelectMDx for Prostate Cancer test included in the 2020 National Comprehensive Cancer Network (NCCN) Guidelines for Prostate Cancer Early Detection;
- Completed the fourth quarter with the second consecutive sequential increase in billable volume for both its ConfirmMDx[®] and SelectMDx[®] tests;
- Continued focus on operating discipline resulting in an improvement in collections and capital allocation; and
- Initiation and advancement of our best-in-class Prostate Cancer menu expansion into Active Surveillance with our renewed engagement and focus on research and development.

“We believe these results represent clear validation that the fundamental growth drivers and value that were communicated prior to the pandemic have been instilled in our organization. Furthermore, the redesigned approach of our salesforce to remain highly engaged and utilize our advanced digital marketing strategy with the urology community, will become evident as the pandemic lifts and patient flow returns.”

Highlights for the quarter and full year ended December 31, 2020

ConfirmMDx

- For the fourth quarter ended December 31, 2020, billable test volume was up 3% to 3,704 versus 3,579 for the third quarter ended September 30, 2020
- For the year ended December 31, 2020, billable test volume was down 18% to 14,945 versus 18,195 for 2019

SelectMDx

- SelectMDx for Prostate Cancer test has been included in the 2020 National Comprehensive Cancer Network (NCCN) Guidelines for Prostate Cancer Early Detection
- For the fourth quarter ended December 31, 2020, billable test volume was up 6% to 3,472 versus 3,267 for the third quarter ended September 30, 2020
- For the year ended December 31, 2020, billable test volume was down 39% to 13,201 versus 21,699 for 2019

Summary of Billable Test Volume by Product

Product	Year Ended December 31,		
	2020	2019	% Change
ConfirmMDx	14,945	18,195	(18)%
SelectMDx	13,201	21,699	(39)%

Product	Quarter Ended December 31,		
	2020	2019	% Change
ConfirmMDx	3,704	5,158	(28)%
SelectMDx	3,472	4,898	(29)%

Financial Highlights for the year ended December 31, 2020

- Total revenue for 2020 of \$18.5 million, down 16% from pro-forma 2019 revenues of \$21.9 million and up 57% from 2019 reported revenues of \$11.8 million (refer to press release issued on February 26, 2020 for details on prior year one-time adjustment)
- Operating expenses for 2020 were \$35.2 million, an improvement of \$8.0 million compared to operating expenses of \$43.2 million for 2019. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation, operating expenses for 2020 were \$30.3 million, an improvement of \$2.4 million, or 7%, over 2019
- Cash and cash equivalents of \$16.0 million as of December 31, 2020. In January 2021, the Company successfully completed a EUR 25 million (approximately \$30.4 million) capital increase, bringing pro-forma year-end cash and cash equivalents to \$46.4 million

Financial review for the year ended December 31, 2020

USD in thousands (except per share data) Unaudited	Year Ended December 31,				
	2020	2019 Pro-forma ¹	2019	2020 vs. 2019 Pro- forma ¹	2020 vs. 2019
Product revenue	18,064	21,521	11,443	(16)%	58%
Royalties, patents and other income	396	342	342	16%	16%
Total Revenue	18,460	21,863	11,785	(16)%	57%
Cost of goods	(10,416)	(11,755)	(11,755)	(11)%	(11)%
Gross Profit	8,044	10,108	30	(20)%	–
Operating expenses	(35,167)	(43,199)	(43,199)	(19)%	(19)%
Operating loss	(27,123)	(33,091)	(43,169)	(18)%	(37)%
Net loss	(28,662)	(33,022)	(43,100)	(13)%	(33)%
Basic and diluted loss per share	(0.34)	(0.53)	(0.69)	(35)%	(50)%

¹Excluding the effect of change of estimate of \$10.1 million (refer to February 26, 2020 press release for details)

Total revenue for 2020 was \$18.5 million compared to total revenue of \$11.8 million for 2019. Revenues for 2019 were impacted by a one-time adjustment of \$10.1 million, which was primarily related to management's decision to reduce the amount of time it carries accounts receivable from 24 months to 12 months. This adjustment is further detailed in the 2019 year-end results press release dated February 26, 2020. Excluding this one-time adjustment, 2020 revenues would have declined 16% compared to 2019 pro-forma revenues of \$21.9 million, due to the COVID-19 pandemic.

Gross profit on products and services for 2020 was \$8.0 million versus a gross profit of \$0 for 2019. Excluding the 2019 one-time adjustment, gross profit on products and services for 2020 decreased 20% compared to pro-forma 2019 gross profit. This decline was primarily the result of the decline in revenues.

Total operating expenses in 2020 were \$35.2 million, an improvement of \$8.0 million over 2019. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation, operating expenses for 2020 were \$30.3 million, an improvement of \$2.4 million, or 7%, over 2019. Operating loss for 2020 was \$27.1 million, a decrease of \$16.0 million compared to an operating loss of \$43.2 million for 2019. Excluding the 2019 one-time adjustment, operating loss for 2020 decreased 18% compared to 2019 pro-forma operating loss, primarily the result of strong operating discipline as well as a decrease in non-cash expenses of depreciation and amortization.

Cash collections from ConfirmMDx and SelectMDx amounted to \$21.0 million, a decrease of 12% compared to 2019, despite larger decreases in billable volume due to COVID-19. Total cash burn for 2020 was \$22.9 million, representing a reduction of \$0.6 million in cash burn compared to \$23.5 million in 2019. Cash and cash equivalents as of December 31, 2020 were \$16.0 million.

Outlook for 2021

Michael K. McGarrity, CEO of MDxHealth, commented: “While the dynamics of the pandemic make it difficult to provide guidance at this time, we are confident that we have advanced adoption of our menu of SelectMDx and ConfirmMDx into the urology market, and that adoption of our product menu as the standard of care in the diagnostic pathway of patients being worked up and suspected of prostate cancer, is taking hold and will drive long term growth beyond 2021.

“In addition, we are now focused on advancing our menu into Active Surveillance (AS) of prostate cancer with the development of our AS-MDx and MonitorMDx tests. These two menu additions would provide clinically actionable results for clinicians evaluating patients for active surveillance. This is a well characterized market opportunity to monitor patients in active surveillance where the standard of care is an annual biopsy. We are confident that we can deliver a less invasive actionable solution.

“We believe these initiatives, coupled with our current menu, will allow MDxHealth to be the only company in the space that affords clinicians a menu of advanced tests to take a patient from positive PSA screen all the way through the diagnostic pathway continuum of care with clinical confidence.

“We are committed to continue to advance the diagnosis and treatment of prostate cancer and our commitment to growth and value creation for all of our stakeholders, including patients, customers, employees and shareholders.”

Subsequent Events

On January 21, 2021, the Company announced the successful pricing of its capital increase with the offering of new ordinary shares. The Company raised EUR 25.0 million (approximately USD 30.4 million) in gross proceeds by means of a private placement of 27,777,777 new shares (being approximately 30.63% of the Company's outstanding shares) at an issue price of EUR 0.90 per share through an accelerated bookbuild offering. The net proceeds of this capital increase will be used to drive further commercial focus and execution, to advance the Company's corporate strategy and for general corporate purposes.

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 08:00am CET / 07:00am GMT. 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: 7873716.

UK / International: 0800 358 6377 / 323-289-6576

Belgium: 0800 58228

The Netherlands: 0800 023 1436

US: 800-437-2398

Webcast: <http://public.viavid.com/index.php?id=143771>

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

2021 Reporting Calendar

- April 21: Q1-2021 business update
- April 28: Online publication of Annual Report 2020
- May 27: Annual General Meeting
- August 26: Publication of H1-2021 results
- October 21: Q3-2021 business update

About MDxHealth

MDxHealth is a commercial-stage, innovative healthcare 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, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US 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 audit procedures with respect to the Company's consolidated financial statements, prepared in accordance with the International Financial Reporting Standards as adopted in the European Union, 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 2021.

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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. 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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