

MDxHealth Reports Financial Year 2019 Results and Provides Outlook for 2020

Conference call with Q&A today at 09:00 CET / 08:00 GMT, details provided below

IRVINE, CA, and HERSTAL, BELGIUM – February 26, 2020 – MDxHealth SA (Euronext: MDXH.BR), a commercial-stage innovative molecular diagnostics company, today announced its financial results for the year ended December 31, 2019 and provided a business update and outlook for 2020.

Michael K. McGarrity, CEO of MDxHealth, commented: “2019 has been a transformational year for MDxHealth, focused on assessing our business and operating execution with the goal of demonstrating evidence of the turnaround required to deliver results that are sustainable and will build value for all of our stakeholders.

“We are confident that evidence of this turnaround is reflected in our results and 2020 outlook, as noted below:

- Q4-2019 ConfirmMDx unit growth of 22% over Q4-2018
- 2019 SelectMDx unit growth of 61% over 2018 as well as issuance of draft LCD
- Cash operating expenses down \$12.3 million, a 27% improvement over 2018
- Q4-2019 use of cash of \$3.9 million, reflecting improved operating discipline and cash collections
- 2020 projected unit growth of over 20% for ConfirmMDx and SelectMDx

“We believe these results, and our positive view forward, reflect a strengthening and refocus of the Company’s commercial organization, significant strengthening of the leadership team and greater and sustainable fiscal discipline across our operations. We remain confident that these changes, alongside our clear strategic focus will drive sustainable growth.”

Highlights for the quarter and full year ended December 31, 2019

ConfirmMDx

- For the quarter ended December 31, 2019, billable test volume was up 22% to 5,158 versus 4,219 for the same period last year
- For the year ended December 31, 2019, billable test volume was down 5% to 18,195 versus 19,194 for 2018

SelectMDx

- Positive draft Local Coverage Determination (LCD) for SelectMDx was released on August 22, 2019, which will provide coverage for qualified Medicare patients throughout the United States. The final LCD is expected in H1 2020
- For the quarter ended December 31, 2019, global billable test volume was up 14% to 4,898 versus 4,294 for the same period last year
- For the year ended December 31, 2019, global billable test volume was up 61% to 21,669 versus 13,447 for 2018
- MDxHealth entered into an agreement with a global diagnostics company to commence a joint development program for SelectMDx on its decentralized point-of-care system, with business and commercial terms to be further determined

Business

- Strengthened management team with the appointments of Michael K. McGarrity as Chief Executive Officer, John Bellano as Chief Commercial Officer and Ron Kalfus as Chief Financial Officer
- Timothy Still appointed as a Non-Executive Director of the Company in November 2019

Summary of billable test volume by product

Territory	Products	Year Ended December 31,		
		2019	2018	% Change
U.S.	ConfirmMDx	18,195	19,194	(5)%
	SelectMDx	16,972	10,688	59%
E.U.	SelectMDx	4,727	2,759	71%

Territory	Products	Quarter Ended December 31,		
		2019	2018	% Change
U.S.	ConfirmMDx	5,158	4,219	22%
	SelectMDx	3,554	3,438	3%
E.U.	SelectMDx	1,344	856	57%

Financial Highlights for the year ended December 31, 2019

- Management has significantly revised its collections estimates for aged accounts receivables, having a negative impact of \$10.1 million on 2019 revenues
 - Management considers this significant revision to collection estimates as a one-time adjustment, primarily reflecting a reduction in the length of time the Company carries accounts receivable from 24 months to 12 months
 - This one-time adjustment brings the Company's revenue recognition in line with updated collection experience and reflects the Company's prioritization of accounts receivable aged 12 months or less
 - This change of estimate does not impact past, and will not impact future units, cash, or underlying reimbursement levels
- Excluding this one-time adjustment, 2019 product revenues, on a pro-forma basis, would have been \$21.5 million, a reduction of 22% from last year, primarily due to the decline in units related to non-recurring volume in the first half of 2018
- Operating expenses for 2019 were \$43.2 million, an improvement of \$5.6 million compared to operating expenses of \$48.8 million for 2018. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation, operating expenses for 2019 were \$32.6 million, an improvement of 12.3 million, or 27%, over 2018
- Cash and cash equivalents of \$22.1 million as of December 31, 2019, following an equity capital increase of €9 million, or approximately \$10 million, as well as a loan facility in the amount of €9 million, or approximately \$10 million, with Kreos Capital

Outlook for 2020

The proven reliability of MDxHealth's technology is well established with a clearly validated value proposition. Management remains confident that MDxHealth's clear strategic focus and experience-based execution will drive growth, as noted below:

- Continued utilization of ConfirmMDx into the Company's current customer base with a well-trained and high-performance sales culture

- Visibility to broaden coverage of SelectMDx, based on well characterized adoption and demonstrated clinical utility, further evidenced by the recently issued draft LCD from Medicare in the U.S.
- Focused approach to drive significant additional adoption of SelectMDx

Based on these drivers, management projects the following operating results for 2020:

- Growth of 20%-25% in ConfirmMDx billed unit volume and growth of 25%-30% in SelectMDx global billed unit volume
- Revenues of \$27-\$30 million, representing an increase of 23%-37% over 2019 pro-forma revenue of \$21.9 million

Michael K. McGarrity CEO of MDxHealth additionally commented, “We are very positive on our outlook and expect to deliver on our guidance of significant growth for 2020. I am also very confident that the measures we took with regard to our revised estimates on aged accounts receivable will provide for more predictable and projectable results for the business.”

Financial review for the year ended December 31, 2019

USD in thousands (except per share data) Unaudited	Year Ended December 31,				
	2019 Pro-forma ¹	2019	2018	2019 Pro- forma ¹ vs. 2018	2019 vs. 2018
Product revenue	21,521	11,443	27,710	(22)%	(59)%
Royalties, patents and other income	342	342	687	(50)%	(50)%
Total Revenue	21,863	11,785	28,397	(23)%	(58)%
Cost of goods	(11,755)	(11,755)	(11,652)	(1)%	(1)%
Gross Profit	10,108	30	16,745	(40)%	(100)%
Operating expenses	(43,199)	(43,199)	(48,843)	12%	12%
Operating loss	(33,091)	(43,169)	(32,098)	(3)%	(34)%
Net loss	(33,022)	(43,100)	(32,450)	(2)%	(33)%
Basic and diluted loss per share	(0.53)	(0.69)	(0.56)	6%	(23)%

¹Excluding the effect of the significant change of estimate of \$10.1 million

Total revenue for 2019 was \$11.8 million compared to total revenue of \$28.4 million for 2018. Revenues for 2019 were impacted by a one-time adjustment of \$10.1 million following a significant change of estimates primarily related to management’s decision to reduce the length of time it carries accounts receivable from 24 months to 12 months. Excluding this one-time adjustment, 2019 revenues, on a pro-forma basis, would have been \$21.9 million, a reduction of 23% from last year, primarily due to the decline in units related to non-recurring volume in the first half of 2018. Revenue from ConfirmMDx represented over 90% of product revenue. This change of estimate did not impact past, and will not impact future units, cash, or underlying reimbursement levels.

Gross profit on products and services for 2019 was \$0.0 principally due to the one-time adjustment. Excluding the one-time adjustment, gross profit on products and services, on a pro-forma basis, would have been \$10.1 million, a decline of \$6.6 million from 2018. This decline was primarily the result of the decline in revenues.

Total operating expenses in 2019 were \$43.2 million, an improvement of \$5.6 million over 2018. Excluding non-cash expenses such as depreciation, amortization and stock-based compensation, operating expenses for 2019 were \$32.6 million, an improvement of \$12.3 million, or 27%, over 2018. Operating loss for 2019 was \$43.2 million, an increase of \$11.1 million compared to an operating loss of \$32.1 million for 2018. Excluding the one-time adjustment, 2019 operating loss, on a pro-forma basis, would have been \$33.1 million, an

increase of \$1.0 million over 2018, primarily the result of the decline in revenues as well as an increase in non-cash expenses of amortization of intangible assets, partially offset by the savings in operating expenditures.

Cash collections from ConfirmMDx and SelectMDx amounted to \$23.7 million, a decrease of 11% compared to 2018. The cash use for 2019 was \$23.5 million, of which \$1.3 million were H1-2019 non-recurring restructuring charges, and actual operating cash use was \$22.2 million. This represents a reduction of \$10.8 million in operating burn compared to \$33.0 million in 2018. Cash use in the fourth quarter ended December 31, 2019, was \$3.9 million, reflecting continued operating discipline and improved cash collections. Cash and cash equivalents as of December 31, 2019 were \$22.1 million.

Based on the Company's current cash position and its projected revenues and collections, management believes that it has sufficient cash through the fourth quarter of 2020. Furthermore, the Company is evaluating all financing options, including non-dilutive funding, to extend its cash runway.

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 09:00am CET / 08:00am 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: 3169697

UK / International: +44 (0) 2071 928000

Belgium: 024009874

The Netherlands: 0207143545

US: 1-631-510-7495

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

2020 Reporting Calendar

- April 21: Q1-2020 business update
- April 28: Online publication of annual report 2019
- May 28: Annual General Meeting
- August 26: Publication of H1-2020 results
- October 21: Q3-2020 business update

About MDxHealth

MDxHealth is a multinational 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 partially 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 2020.

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