

## MDxHealth Reports Half Year 2019 Financial Results and Strategic Update

*Conference call with Q&A today at 11:00 CEST / 10:00 BST, details provided below*

**IRVINE, CA, and HERSTAL, BELGIUM** – August 29, 2019 – MDxHealth SA (Euronext: MDXH.BR), a commercial-stage innovative molecular diagnostics company, today announced its financial results for the half year ended June 30, 2019, and an update on its corporate strategy, vision and outlook.

### Strategic Review Update

Michael McGarrity appointed as Chief Executive Officer in February 2019.

Key strategic areas of focus and execution:

- **ConfirmMDx<sup>®</sup>** – refocus and engage the sales organization in driving ConfirmMDx utilization into established customer base of urologists
- **SelectMDx<sup>®</sup>** – advance U.S. coverage for Medicare and commercial payors based on already validated market opportunity and clinical utility
- Drive focus on operating discipline with regards to P&L and operating expenses
- Evaluate deep product pipeline of previous R&D efforts and additional applications of licensed and proprietary biomarkers for additional value creation

Progress to date against these focus areas includes:

- Leadership team significantly strengthened with appointments of John Bellano as Chief Commercial Officer and Ron Kalfus as Chief Financial Officer
- Measures implemented to stabilize and return ConfirmMDx to growth through renewed focus on established customer base
- Management encouraged by adoption rate of SelectMDx liquid biopsy test, and confident in visibility to CMS coverage – evidenced by recent positive draft Local Coverage Determination (LCD) issued August 22, 2019
- Entered into an agreement with a global diagnostics company to commence a joint development program for SelectMDx on the partner's decentralized point-of-care system with business and commercial terms to be further determined
- Continued focus on operational execution and P&L discipline

**Michael McGarrity, CEO of MDxHealth, said:** *“Since joining MDxHealth in February 2019, we have undertaken a comprehensive assessment of the business, with a specific focus on operating and commercial execution. I have been impressed with the significant growth potential of ConfirmMDx and SelectMDx. While we view 2019 as a year of transition associated with the impact of non-recurring volume and revenue, as well as instability in the commercial organization and execution, we are encouraged by our sequential quarterly progress. We now have a clear strategy to stabilise and return ConfirmMDx to growth and unlock the potential of SelectMDx.*

*“As part of our focus on building out market opportunity for our test menu, we are excited to announce that we have entered into an agreement with a global diagnostic company to commence a joint development program for SelectMDx on the partner's decentralized point-of-care system. This agreement is illustrative of the opportunity for the Company to build out SelectMDx as a standard of care in prostate cancer, utilizing our proprietary capabilities to advance the promise of liquid biopsy to aid in the diagnosis and rule-out of prostate cancer. We believe this opportunity preserves SelectMDx's growth in the Urology setting, while opening significant opportunities in the point-of-care setting and the primary care market.*

*“I would also like to comment on the strength of our management team, now fortified by the additions of John*

*Bellano as Chief Commercial Officer and Ron Kalfus as Chief Financial Officer. John is a world class commercial leader with deep and broad experience in the molecular diagnostics space. John has a strong track record of building highly productive teams and bringing value to shareholders. John and I have experience working together and I am certain he will drive accountability, performance and results in our commercial operations.*

*“Ron Kalfus brings extensive expertise in financial operation in both the public and private settings. Ron has extensive experience in the CLIA laboratory business model and will apply this to our best-in-class laboratory operation to drive operating and P&L leverage. I am confident that the value of these important additions to our team will be evident in the very near term.”*

### **Financial Highlights for the period ended 30 June 2019**

- Product revenue of \$10.6 million, down 36% from \$16.6 million in H1 2018, impacted by instability in the commercial organization in the latter part of 2018, as well as non-recurring revenue in H1 2018 from utility studies and out-licensed products
- Sequentially, quarter-over-quarter, product revenue was up 37% from \$4.5 million in Q1 2019 to \$6.1 million in Q2 2019
- Gross profit (excluding royalties and patent income) was \$4.7 million or 44% of product revenue for H1 2019 compared to \$10.0 million or 60% of product revenue for H1 2018. The reduction in gross profit percent is primarily due to the declines in net revenues, impacted by variances in volume, accounts receivable adjustments, and payor mix
- Operating loss of \$13.9 million, an improvement of \$1.1 million over the same period last year
- EBITDA loss of \$12.2 million, an improvement of \$1.3 million over the same period last year, as a result of optimization and focus-driven reductions in operating expenditures
- Cash collections on products of \$11.6 million, down 21% compared to H1 2018
- Cash and cash equivalents of \$12.2 million

### **Operational highlights for the first half of 2019**

#### *ConfirmMDx*

- Billable test volume down 20%, to 8,732 in H1 2019 versus 10,864 in H1 2018. Excluding utility study testing, which increased non-recurring volume last year, our normalized patient billable test volume was down 8%
- Sequentially, quarter-over-quarter billable test volume was stable at 4,379 in Q1 2019 compared to 4,353 in Q2 2019

#### *SelectMDx*

- Global billable test volume of 12,528, up 98% compared to 6,313 in H1 2018. Sequentially, quarter-over-quarter, global billable test volume is up 5% from 6,106 in Q1 2019 to 6,422 in Q2 2019
- US billable test volume of 10,218, up 107% compared to 4,935 in H1 2018

### **Summary of billable test volume by product**

Territory	Products	H1 2019	H1 2018	H1 YoY
		Volume	Volume	% Change
U.S.	ConfirmMDx	8,732	10,864	(20)%
	SelectMDx	10,218	4,935	107%
EU	SelectMDx	2,310	1,378	68%

### **Outlook and Value Creation**

Management has identified several clear value drivers to realize the Company’s growth potential. Management is confident that clear strategic focus, continued disciplined operating expense management

and experience-based execution in these areas of focus will drive revenue growth.

The following areas have been identified as key drivers:

- Proven reliability of MDxHealth’s technology, with a clear validated value proposition and clinical utility, established through both peer reviewed publication and reference-based adoption
- Experienced management team in place to lead focus and execution of initiatives
- Opportunity to drive utilization of ConfirmMDx into the Company’s current customer base with a well-trained and high-performance sales culture
- Visibility to broad coverage of SelectMDx based on the well characterized adoption and demonstrated clinical utility, further evidenced by recently issued draft LCD from Medicare in the U.S.
- Opportunity to drive significant additional adoption of SelectMDx into the alternate site point-of-care and primary care settings  
Explore focused opportunities to monetize and further build value through the Company’s additional menu and biomarker capabilities with strategic partnerships or carve outs

### Financial review for the first half of 2019

Key unaudited consolidated figures for the six months ended June 30, 2019 (thousands of US dollars, except per share data):

	<b>2019</b>	<b>2018</b>	<b>Change</b>	<b>% Change</b>
Product revenue	10,571	16,638	(6,067)	(36)%
Royalties and patent income	302	562	(260)	(46)%
Total Revenue	10,873	17,200	(6,327)	(37)%
Gross Profit	4,964	10,526	(5,562)	(53)%
Operating expenses	(18,827)	(25,478)	6,651	26%
Operating loss	(13,863)	(14,952)	1,089	7%
Net loss	(14,138)	(15,113)	975	6%
Basic and diluted loss per share	(0.24)	(0.27)	0.03	11%

Total revenue for the first half was \$10.9 million compared to total revenue of \$17.2 million during the same period in 2018. Revenue from ConfirmMDx and SelectMDx amounted to \$10.6 million and decreased 31% from \$15.3 million a year earlier. Revenue from ConfirmMDx represented 90% of product revenue.

Operating expenses in the first half of 2019 were \$18.8 million, an improvement of \$6.7 million over the same period last year.

Operating loss and net loss for the first half of 2019 were \$13.9 million and \$14.1 million, respectively, with losses narrowing compared to \$15.0 million and \$15.1 million, respectively, over the same period in 2018 thanks to cost reduction initiatives implemented in late 2018. Excluding royalties, the gross profit on products and services decreased by \$5.3 million to \$4.7 million, primarily due to the decline in revenues.

Cash and cash equivalents as of June 30, 2019 were \$12.2 million. Cash collections from ConfirmMDx and SelectMDx amounted to \$11.6 million, a decrease of 21% compared to last year. The cash burn for the period was \$14.0 million, of which \$1.3 million was H1 2019 non-recurring restructuring charges, and actual operating cash burn was \$12.7 million compared to \$15.0 million in the previous year. Based on the Company’s current cash position and its projected revenues and collections, management believes that it has sufficient cash into the first 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 11:00am CEST / 10:00 BST. 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 confirmation code 2591505.

UK:	+44 (0) 207 1928 000
Belgium:	0800 487 40
The Netherlands:	0800 024 95 57
US:	1866 966 13 96

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

## 2019 Reporting Calendar

- Second interim trading update: November 11, 2019

## 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](http://mdxhealth.com) and follow us on social media at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth), [facebook.com/mdxhealth](https://facebook.com/mdxhealth) and [linkedin.com/company/mdxhealth](https://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 2019, prepared in accordance with the International Financial Reporting Standards as adopted in the European Union, have been substantially completed. The aforementioned condensed consolidated financial statements are expected to be made available to the public via the Company's website in September 2019 at [www.mdxhealth.com](http://www.mdxhealth.com)

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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*

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