



## bioMérieux – Second-Quarter 2016 Business Review

- ▼ **Strong growth in sales, up 10.9%, at constant exchange rates and scope of consolidation in the first half of 2016:**
  - Sales reached €1,001 million
  - Up 7.2% as reported
- ▼ **Growth continued to be led by the Americas in the second quarter, supported by the return to faster gains in the Asia-Pacific region**
- ▼ **All of the clinical and industrial lines contributed to consolidated growth**
- ▼ **Excellent 62% increase in FilmArray<sup>®</sup> sales in the second quarter**

Alexandre Mérieux, Chief Executive Officer, said: "bioMérieux achieved €1 billion in sales right from the first half, confirming that 2016 has gotten off to a good start. The sustained momentum in the Americas, boosted by the return to faster growth in the Asia-Pacific region, particularly in China, more than offset the modest gains in the EMEA region, helping to drive organic growth in sales of nearly 11% for the six-month period. As was the case in 2015, second-half growth is expected to come in slightly below the first-half performance and set us on a favorable course to fulfilling our ambitions."

**Marcy l'Etoile (France), July 18, 2016** – bioMérieux, a world leader in the field of *in vitro* diagnostics, today released its quarterly business review for the six months ended June 30, 2016.

### SALES

Consolidated sales rose to €1,001 million in the first six months of 2016 from €933 million in the year-earlier period. This 7.2% reported increase included a negative currency effect of around €26 million as well as the impact of deconsolidating bioTheranostics as from January 1. Year-on-year organic growth (i.e., at constant exchange rates and scope of consolidation) came to 10.9%, led by an acceleration in sales of FilmArray<sup>®</sup> for around 450 bp and of BioFire Defense solutions for 100 bp.

#### Analysis of sales

*In € millions*

<b>Sales – Six Months Ended June 30, 2015</b>	<b>933</b>		
Currency effect	(25.7)	-2.8%	
Organic growth (at constant exchange rates and scope of consolidation)	100.8	+10.9%	} +10.1%
Changes in scope of consolidation*	(7.6)	-0.8%	
<b>Sales – Six Months Ended June 30, 2016</b>	<b>1,001</b>	<b>+7.2%</b>	

\* Deconsolidation of bioTheranostics and consolidation of Applied Maths as of January 1, 2016

**NB:** Unless otherwise stated, growth is expressed year-on-year at constant exchange rates and scope of consolidation (like-for-like).

The breadth and balance of bioMérieux's product portfolio helped to drive year-on-year organic growth of 10.3% in the second-quarter of 2016, led by the fast development of the FilmArray<sup>®</sup> line, which saw sales rise by around 70% compared with the year-earlier period. In addition, while every region contributed to consolidated growth, the Americas remained the primary driver thanks to robust performances by bioMérieux Inc., BioFire Diagnostics and BioFire Defense. An adverse currency effect reduced reported sales by €19 million, of which €4 million due to the US dollar compared with a €4 million favorable impact in the first three months of the year.

Sales for the second quarter and first half of 2016 may be summarized by region as follows:

Sales by Region In € millions	Q2 2016	Q2 2015	% change as reported	% change at constant exchange rates and scope of consolidation	6 months ended June 30, 2016	6 months ended June 30, 2015	% change as reported	% change at constant exchange rates and scope of consolidation
Europe <sup>1</sup>	210.3	210.9	-0.3%	+1.7%	417.1	414.9	+0.5%	+2.1%
Americas	205.3	181.9	+12.9%	+18.8%	418.1	358.4	+16.7%	+20.6%
North America	172.5	147.1	+17.3%	+20.3%	355.4	291.8	+21.8%	+22.1%
Latin America	32.9	34.8	-5.6%	+12.5%	62.7	66.6	-5.8%	+14.0%
Asia-Pacific	95.0	86.9	+9.3%	+13.9%	162.4	148.8	+9.1%	+12.5%
<b>Total sales from the regions</b>	<b>510.6</b>	<b>479.6</b>	<b>+6.5%</b>	<b>+10.4%</b>	<b>997.7</b>	<b>922.1</b>	<b>+8.2%</b>	<b>+11.0%</b>
bioTheragnostics		4.8				8.9		
Applied Maths	0.7				1.3			
R&D-related revenue	1.0	0.8			1.8	2.2		
<b>TOTAL</b>	<b>512.3</b>	<b>485.3</b>	<b>+5.6%</b>	<b>+10.3%</b>	<b>1,000.8</b>	<b>933.2</b>	<b>+7.2%</b>	<b>+10.9%</b>

<sup>1</sup>Including the Middle East and Africa.

- ▼ Operations in the **Americas** (42% of the YTD consolidated total), continued to deliver very robust gains in the second quarter of 2016, with sales rising 18.8% year-on-year to €205 million for the period. Sales ended the first half at €418 million, up 20.6% year-on-year.
  - Sales in **North America** (36% of the YTD consolidated total) rose by more than 20% year-on-year in the second quarter, led by all of the Group's product lines. The primary driver was the FilmArray<sup>®</sup> range, along with the increasingly wider take-up of the VIDAS<sup>®</sup> B•R•A•H•M•S PCT™ test, fast growth in sales of the dedicated industrial application lines and firm demand for the microbiology lines.
  - In **Latin America**, sales climbed 12.5% year-on-year to €33 million in the second quarter. All countries in the region made firm gains, with Brazil, Argentina and Colombia enjoying double-digit growth. On the other hand, reported growth continued to be dampened by the negative currency effect.
- ▼ Sales in the **Europe–Middle East–Africa region** (42% of the YTD consolidated total) came to €210 million for the second quarter, up 1.7% year-on-year, and to €417 million for the first half, up 2.1% year-on-year.
  - In **Western Europe** (36% of the YTD consolidated total), sales were nearly unchanged year-on-year in France and Italy, where the market environment remained challenging, but declined in the Nordic countries off of high prior-year comparatives. Compared with the first quarter, sales maintained their steady, solid pace in Spain and Switzerland and gained new momentum in Germany.
  - As expected, sales growth slowed in the **Eastern Europe–Middle East–Africa region** in the second quarter, to 1.9% year-on-year, with sustained expansion in Russia, Turkey and South Africa more than offsetting a certain softening in Africa and the Middle East.

- ▼ In the **Asia-Pacific** region (16% of the YTD consolidated total), sales ended the second quarter at €95 million, up 13.9% year-on-year, and the first half at €162 million, up 12.5% year-on-year.
  - Operations in **China** represented the main growth engine, fueled by both clinical and industrial applications. Rapid growth in reagent sales helped to align the instrument/reagent sales mix more closely with the Group's over the first half.
  - Sales in **India** continued to expand, climbing more than 20% compared to second-quarter 2015 when growth was more moderate.

Sales for the second quarter and first half of 2016 may be summarized by application as follows:

Sales by Application In € millions	Q2 2016	Q2 2015	% change as reported	% change at constant exchange rates and scope of consolidation	6 months ended June 30, 2016	6 months ended June 30, 2015	% change as reported	% change at constant exchange rates and scope of consolidation
<b>Clinical Applications</b>	<b>405.3</b>	383.8	+5.6%	<b>+9.6%</b>	<b>798.2</b>	740.6	+7.8%	<b>+10.6%</b>
Microbiology	219.9	218.2	+0.8%	<b>+4.9%</b>	426.7	416.3	+2.5%	<b>+5.7%</b>
Immunoassays <sup>1</sup>	115.1	112.6	+2.1%	<b>+6.1%</b>	219.1	210.2	+4.2%	<b>+7.2%</b>
Molecular biology <sup>2</sup>	69.3	50.3	+37.6%	<b>+42.0%</b>	149.5	108.0	+38.5%	<b>+39.4%</b>
Others	1.1	2.6	-57.0%	<b>-57.7%</b>	2.8	6.1	-53.4%	<b>-54.2%</b>
<b>Industrial Applications</b>	<b>95.5</b>	90.3	+5.8%	<b>+9.4%</b>	<b>181.5</b>	172.8	+5.0%	<b>+7.8%</b>
bioTheranostics		4.8				8.9		
BioFire Defense	9.8	5.6	+73.9%	<b>+76.6%</b>	18.0	8.7	x2.1	<b>x2.1</b>
Applied Maths	0.7				1.3			
R&D-related revenue	1.0	0.8			1.8	2.2		
<b>TOTAL</b>	<b>512.3</b>	485.3	+5.6%	<b>+10.3%</b>	<b>1,000.8</b>	933.2	7.2%	<b>10.9%</b>

<sup>1</sup>Including VIDAS<sup>®</sup>: up 8.7% at constant exchange rates and scope of consolidation in Q2; up 9.1% in H1

<sup>2</sup>Including FilmArray<sup>®</sup> sales in an amount of €52 million in Q2 and €113 million in H1.

- ▼ Sales of **clinical applications**, which account for approximately 80% of the consolidated total, stood at €405 million for the second quarter, up 9.6% year-on-year, and at €798 million for the first half, up 10.6% year-on-year.
  - In **microbiology**, sales of the blood culture lines continued to accelerate over the second quarter, gaining almost 15% over the period. At the same time, growth in VITEK<sup>®</sup> identification and AST systems slowed, due mainly to a dip in instrument sales that offset a mid-single digit increase on the reagents side.
  - In the **immunoassays** segment, the VIDAS<sup>®</sup> line enjoyed another quarter of fast growth, led by such high medical-value tests as the VIDAS<sup>®</sup> B•R•A•H•M•S PCT™ test, which recently received FDA clearance to extend its use to managing sepsis patients, even as competitors are starting to enter the U.S. market.
  - **Molecular biology** sales surged a further 42% in the second quarter, led by the still remarkable success of the FilmArray<sup>®</sup> line. The new high-throughput FilmArray<sup>®</sup> Torch system attracted a great deal of IVD industry attention during its presentation at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in April 2016 and at the American Society of Microbiology (ASM) meeting in June 2016. The first instruments were delivered and installed during the second quarter. Fast-growing demand for the system's GI panel and early success of the Meningitis-Encephalitis panel prove that a growing percentage of customers are using FilmArray<sup>®</sup> solutions other than the Respiratory panel. Lastly, international sales are continuing to rise, with their contribution outside the United States representing 9% of the total in the first half compared with 6% a year earlier.

NB: Unless otherwise stated, growth is expressed year-on-year at constant exchange rates and scope of consolidation (like-for-like).

- Sales of **industrial applications**, which represent around 18% of the consolidated total, amounted to €96 million in the second quarter, up 9.4% on the prior-year period, and to €181 million in the first half, up 7.8% year-on-year. This satisfactory performance was supported by all of the technologies offered by bioMérieux in this field, particularly the VIDAS<sup>®</sup> immunoassay solutions for the rapid detection of food pathogens and, in the microbiology segment, the VITEK<sup>®</sup> bacterial identification systems and the culture media lines.
- In the first half, the product mix was improved by organic growth in sales of **reagents** and **services**, which rose by 11.7% year-on-year, compared to a 3% gain in instruments.

## OTHER INFORMATION

### Installed base

The installed base at June 30, 2016 stood at approximately 86,700 instruments, including 3,100 FilmArray<sup>®</sup> units. This represented an increase of around 2,200 new instruments over the first half, of which around 600 FilmArray<sup>®</sup> units.

### Net debt

**Net debt** stood at €265 million at June 30, 2016 after payment of the dividend and of Hyglos acquisition price, versus €219 million at December 31, 2015.

## SECOND-QUARTER OPERATING HIGHLIGHTS

### bioMérieux acquires Hyglos and expands its offering to the detection of endotoxins in pharmaceutical products

bioMérieux, the world leader in industrial microbiological control, announced on June 1, 2016 the acquisition of Hyglos, a Bernried, Germany-based company specializing in the detection of endotoxins. Founded in 2009, Hyglos has unique, recognized expertise in the development and production of recombinant proteins used to detect endotoxins in pharmaceutical products. The total consideration paid by bioMérieux to acquire all outstanding Hyglos shares will amount to a maximum of €24 million, phased over the next three years.

### FDA clears expanded use of VIDAS<sup>®</sup> B•R•A•H•M•S PCT™ test for managing sepsis patients with elevated risk of mortality

On June 28, 2016, the U.S. Food and Drug Administration (FDA) issued 510(k) clearance to expand the use of the VIDAS<sup>®</sup> B•R•A•H•M•S PCT™ (Procalcitonin) assay using the change in PCT levels over time to aid in the management of sepsis patients after the initial diagnosis. Based on a recent study, monitoring PCT levels over four days (96 hours) can help doctors determine which septic patients are at the greatest risk of death, enabling them to quickly adjust the medical care for those patients.

### Launch of the VIDAS<sup>®</sup> anti-Müllerian hormone (AMH) test

The VIDAS<sup>®</sup> AMH test was CE-marked in June 2016 and is now commercially available. Anti-Müllerian hormone (AMH) testing assesses the ovarian follicle reserve in women represents a significant advance in the treatment of female infertility, helping to optimize the protocols for medically assisted procreation by personalizing the different stages of ovarian stimulation the different stages of ovarian stimulation. In addition, AMH can play a role in the diagnosis of ovarian dysfunction (caused for example by polycystic ovary syndrome). The new test enhances the existing range of VIDAS<sup>®</sup> women's health solutions for the diagnosis and follow-up of the most important types of mother-to-fetus infection and for the investigation of reproductive hormone dysfunction.

### Income tax expense

The Group's effective tax rate at June 30, 2016 will be impacted by the recognition of an expense related to previous years for a tax dispute in a net amount of about €6 million.

## SUBSEQUENT EVENTS

### ▼ Production and quality system

On July 8, 2016, France's ANSM drug regulatory agency notified bioMérieux that it had lifted the injunction letter issued in February 2015 following the completion of compliance work on certain production units at the facility in Craponne, France.

### ▼ New release of bioMérieux blood culture system BacT/ALERT® Virtuo™ gets CE-marked and is submitted to the FDA clearance for 510(k) clearance

bioMérieux announced the CE-marking of an updated release with enhanced features to its newest blood culture automated system BacT/ALERT® VIRTUO™.

The new CE-marked release of BacT/ALERT® VIRTUO™ features blood level detection which directly measures the blood volume added to each blood culture bottle at loading time, to ensure compliance with collection of the recommended blood volume. The new generation blood culture system, BacT/ALERT® VIRTUO™, can combine up to three additional incubator subunits connected to a command module in a single BacT/ALERT® VIRTUO™ bank. A BacT/ALERT® VIRTUO™ bank is an integrated configuration, scalable from 428 to 1,712 cells capacity and enables the management of high volume testing of up to 100,000 bottles/year with a single entry point.

The system has also been submitted to the U.S. Food and Drug Administration (FDA) for 510(k) clearance.

### ▼ Pathogen identification capability on VITEK® MS broadened to mycobacteria, *Nocardia*, and molds

bioMérieux has announced the launch of the first CE-marked database and reagent kits for the identification of mycobacteria, *Nocardia*, and molds in a mass spectrometry system. These difficult-to-identify organisms require days or weeks of specific culture conditions for appropriate growth and subsequent advanced methods for reliable identification to species level.

The VITEK® MS extended database now enables the identification within minutes of 1,046 species representing 15,172 distinct strains of bacteria, yeasts and molds. It is part of a fully integrated solution combining identification with VITEK® MS and antibiotic susceptibility testing with VITEK® 2, resulting in superior workflow management.

### ▼ Kirk Ririe appointed to the bioMérieux Executive Committee as Corporate Vice President, Innovation

Kirk Ririe, co-founder and former Chief Executive Officer of BioFire, was one of the pioneers in the development of FilmArray® technology. Formerly Chief Executive Officer of BioFire Defense, Kirk is now a member of the Group's Executive Committee, and will lead the development of innovative solutions that will help to strengthen bioMérieux's competitive positioning in the fight against infectious diseases.

## 2016 OBJECTIVES

bioMérieux will now release its objectives concerning full-year organic sales growth and contributive operating income before non-recurring items at half-year or full-year publication. 2016 objectives will therefore be published next August 31.

## INVESTOR CALENDAR

First-half 2016 results	August 31, 2016, before start of trading
Third-quarter 2016 sales:	October 20, 2016, before start of trading

*The above forward-looking statements are based, entirely or partially, on assessments or judgments that may change or be modified, due to uncertainties and risks related to the Company's economic, financial, regulatory and competitive environment, notably those described in the 2015 Registration Document. Accordingly, the Company cannot give any assurance nor make any representation as to whether the objectives will be met. The Company does not undertake to update or otherwise revise any forecasts or objectives presented herein, except in compliance with the disclosure obligations applicable to companies whose shares are listed on a stock exchange.*

## ABOUT BIOMÉRIEUX

### *Pioneering Diagnostics*

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2015, revenues reached €1,965 million with 90% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the Euronext Paris stock market

(Symbol: BIM/Reuters: BIOX.PA/Bloomberg: BIM.FP – ISIN: FR0010096479)

Corporate website: [www.biomerieux.com](http://www.biomerieux.com). Investor website: [www.biomerieux-finance.com](http://www.biomerieux-finance.com)

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