

bioMérieux – Business review for the nine months ended September 30, 2015

# Robust growth in nine-month sales:

- Sales reached €1,412 million
- Up 18.3% as reported
- Up 8.3% at constant exchange rates and scope of consolidation
- Solid momentum in the Americas and EMEA<sup>1</sup> regions in the third quarter
- Significant operational advances:
  - FDA clearance of the 4<sup>th</sup> FilmArray<sup>®</sup> panel: Meningitis/Encephalitis
  - Commercial launch of VIDAS<sup>®</sup> 3 in the United States
  - Deployment of capital expenditures as planned
- Organic sales growth objective should end the year around 6.5%

Alexandre Mérieux, Chief Executive Officer, said: "bioMérieux continued to drive very satisfactory organic sales growth over the first nine months of the year, with a more than 8% gain for the period. This sales performance reflects our effectively balanced product portfolio and geographic positions, as well as FilmArray<sup>®</sup>'s remarkable performance. Given this robust growth dynamic and based on our nine-month sales, organic sales growth objective should end the year around 6.5%."

**MARCY L'ETOILE – October 22, 2015** – bioMérieux, a world leader in the field of *in vitro* diagnostics, today released its business review for the nine months ended September 30, 2015.

# SALES

Consolidated sales rose to €1,412 million in the first nine months of 2015 from €1,193 million in the year-earlier period, an increase of 18.3% as reported and of 8.3% at constant exchange rates and scope of consolidation. After nine months of operations, bioMérieux growth excluding BioFire reached 4.5% year-on-year. BioFire contributes by around 400 basis points to the Group's growth.

Analysis of sales In € millions			
Sales - Nine months ended September 30, 2014	1,193		
Currency effect	+111	+9.3%	
Organic growth (at constant exchange rates and scope of consolidation)	+99	+8.3%	
Changes in scope of consolidation <sup>(1)</sup>	+9	+0.7%	+9.0%
Sales - Nine months ended September 30, 2015	1,412	+18.3%	

<sup>(1)</sup>BioFire: sales from January 1 to January 15, 2015 excluded from the organic growth calculation (acquisition date: January 16, 2014) CEERAM: first-time consolidation of sales from this technological start-up acquired in late December 2014.

<sup>1</sup> Europe – Middle East – Africa

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

Third-quarter sales stood at €478 million, an 8.8% year-on-year organic increase that was led by a remarkable performance in North America and the firm momentum in the Eastern Europe – Middle East – Africa region.

Growth during the third quarter fully benefited from the broad portfolio of technologies, particularly FilmArray<sup>®</sup>, which saw a sharp rise in North American sales, and the VIDAS<sup>®</sup> and VITEK<sup>®</sup> lines, which turned in a solid performance.

Sales by Region In € millions	9 months ended Sep 30, 2015	9 months ended Sep 30, 2014	% change as reported	% change at constant exchange rates and scope of consolidation	Q3 2015	Q3 2014	% change as reported	% change at constant exchange rates and scope of consolidation
Europe <sup>(1)</sup>	618.8	595.4	+3.9%	+2.8%	203.8	192.9	+5.6%	+4.9%
Americas	544.3	392.1	+38.8%	+18.0%	186.0	142.4	+30.6%	+16.5%
North America	443.5	299.2	+48.2%	+20.6%	151.7	108.4	+39.9%	+18.4%
Latin America	100.8	92.9	+8.5%	+9.6%	34.2	33.9	+1.0%	+10.3%
Asia-Pacific	229.9	193.5	+18.8%	+4.4%	81.1	73.1	+10.9%	+0.6%
Total sales from the regions	1,393.0	1,181.0	+18.0%	+8.1%	470.9	408.5	+15.3%	+8.1%
bioTheranostics	14.0	7.0	+99.4%	+63.9%	5.1	2.3	+118.2%	+83.0%
R&D-related revenues	4.5	4.7			2.3	1.2		
TOTAL	1,411.5	1,192.7	+18.3%	+8.3%	478.3	412.0	+16.1%	+8.8%

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

- Sales in the Europe Middle East Africa region (44% of the consolidated total) came to €619 million for the period, up 2.8% year-on-year.
  - In Western Europe (38% of the consolidated total), nine-month sales were 1.3% higher compared with the year before. In the third quarter, sales rose by more than 5% year-on-year in Southern Europe, lifted by the good performance in Spain and Portugal. Growth in Northern and Central Europe continued to be driven by the solid results in Germany, the United Kingdom and the Scandinavian countries, while the slowdown in French sales leveled off in a persistently difficult market environment.
  - Sales surged 12% in the Eastern Europe Middle East Africa region which is still significantly hindered by geopolitical tensions, boosted by a firm performance across every country, as well as by a favorable comparison in the third quarter. Third-quarter sales were lifted by a number of one-off tender wins, notably in Lebanon.
- The pace of growth remained very strong in the Americas during the third quarter, with nine-month sales climbing nearly 18% year-on-year to €544 million.
  - In North America (32% of the consolidated total), sales rose by 20.6% year-on-year, led by the remarkable performance of FilmArray<sup>®</sup> and the solid growth in sales of VIDAS<sup>®</sup> B•R•A•H•M•S PCT<sup>™</sup> tests and of the VITEK<sup>®</sup> bacterial identification and antibiotic susceptibility testing lines. Industrial application sales were lifted by sustained demand for the bacterial flora detection and enumeration lines.
  - Third quarter sales in Latin America (7% of the consolidated total) were up 10.3% year-onyear, with solid gains by every subsidiary except in Brazil, where economic difficulties are still weighing on demand.

- In the Asia-Pacific region (17% of the consolidated total), sales came to €230 million for the period, up 4.4% year-on-year.
  - Sales in China retreated 2% in the third quarter as sustained growth in reagent sales failed to
    offset the sharp slowdown in instrument sales during the period, in both clinical and industrial
    applications (except for VIDAS<sup>®</sup>). Next quarter should show an unfavorable basis effect due to
    significantly higher instrument sales during fourth quarter 2014.
  - In the rest of the region, the third-quarter situation varied by country, with sales rising by more than 20% in India but edging back by almost 2% in Japan and South Korea on the same period.

Sales by Application In € millions	9 months ended Sep 30, 2015	9 months ended Sep 30, 2014	% change as reported	% change at constant exchange rates and scope of consolidation	Q3 2015	Q3 2014	% change as reported	% change at constant exchange rates and scope of consolidation
Clinical Applications	1,114.8	940.9	+18.5%	+8.4%	374.3	325.3	+15.0%	+7.9%
Microbiology	632.5	564.2	+12.1%	+4.3%	216.2	199.3	+8.2%	+3.0%
Immunoassays <sup>(1)</sup>	315.9	276.3	+14.3%	+6.1%	105.7	91.3	+15.7%	+9.0%
Molecular Biology <sup>(2)</sup>	158.1	89.1	+77.4%	+46.1%	50.2	31.4	+59.9%	+31.7%
Other	8.3	11.3	-25.2%	-28.0%	2.2	3.3	-31.7%	-35.5%
Industrial Applications	260.3	233.6	+11.4%	+3.7%	87.5	81.0	+7.9%	+2.4%
bioTheranostics	14.0	7.0	+99.4%	+63.9%	5.1	2.5	x 2.2	+83.0%
BioFire Defense	17.9	6.5	x 2.7	x 2.2	9.1	2.1	x 4.4	x 3.7
R&D-related revenue	4.5	4.7			2.3	1.2		
TOTAL	1,411.5	1,192.7	+18.3%	+8.3%	478.3	412.0	+16.1%	+8.8%

Sales for the first nine months and the third quarter of 2015 may be summarized by application as follows:

<sup>(1)</sup>Including VIDAS<sup>®</sup>: up 9.1% over the first nine months and 12.4% in the third quarter, at constant exchange rates and scope of consolidation.

<sup>(2)</sup>Including BioFire Diagnostics sales: €97 million over the first nine months and €30 million in the third quarter.

Sales of **clinical applications** rose by 8.4% year-on-year to €1,115 million.

- Microbiology sales stood at €633 million for the first nine months, up 4.3% primarily on the firm demand for culture media and the VITEK<sup>®</sup> automated ID/AST line of instruments and reagents. Sales of the BacT/ALERT<sup>®</sup> and VIRTUO<sup>™</sup> blood culture lines cooled somewhat in the third quarter due to an unfavorable comparison with the prior-year period, when the return to normal production conditions at the Durham (NC United-States) site made it possible to rebuild part of the customer safety stock inventory.
- In immunoassays, VIDAS<sup>®</sup> sales climbed 9.1% year-on-year. In the third quarter, reagents enjoyed double-digit growth in the Americas and Asia-Pacific regions. In particular, high medical value tests, such as the VIDAS<sup>®</sup> B•R•A•H•M•S PCT<sup>™</sup> test, are still driving the line's expansion, thereby confirming the successful repositioning of VIDAS<sup>®</sup> in clinical biology labs. In addition, instrument sales showed signs of an upturn in the Asia-Pacific region.
- Molecular biology sales amounted to €158 million for the period, an increase of nearly 50% year-on-year. The FilmArray<sup>®</sup> line again turned in a remarkable performance in the third quarter, with cumulative nine-month sales up by about 100% from the prior-year period. The other molecular biology lines showed positive momentum, notably with 13% growth in the ARGENE<sup>®</sup> range of solutions for the management of viral infections in immunocompromised patients.

- Industrial application sales, which represent 18% of the consolidated total, rose by 3.7% to €260 million in the first nine months of 2015. All of the regions contributed to this growth, especially North America. Demand from the agri-foods and pharmaceutical industry improved in the third quarter, particularly for the bacterial flora enumeration technologies (CHEMUNEX<sup>®</sup> and TEMPO<sup>®</sup>).
- Organic growth in sales of reagents and services, which accounted for 91% of the consolidated total, came to 8.4% for the first nine months.

# OTHER INFORMATION

Net debt

**Net debt** amounted to €236 million at September 30, 2015, versus €249 million at December 31, 2014.

# THIRD-QUARTER OPERATING HIGHLIGHTS

### Production and quality system

In June 2015, the US Food and Drug Administration (FDA) re-inspected the St. Louis, MO site and reviewed all of the corrective actions implemented in response to the October 2014 Warning Letter. It determined that there were no repeat observations as regards the Letter. Based on this evaluation, on September 18, the agency issued a Close-Out Letter confirming that its remarks and warnings issued in 2014 had been addressed and encouraging bioMérieux to maintain its efforts to ensure sustained compliance in its operations.

The facilities in Craponne, France and Durham, NC continued to deploy the action plans defined respectively with France's ANSM drug regulatory agency and the FDA to address their observations.

### VIDAS 3 cleared by the FDA and introduced in the United States

On July 9, bioMérieux received 510(k) clearance from the FDA to market VIDAS<sup>®</sup> 3 in the United States. Launched at the American Association for Clinical Chemistry (AACC) Clinical Lab Expo, the new generation VIDAS<sup>®</sup> has received an enthusiastic reception from customers, who appreciate its ease of use, enhanced automation, improved traceability and greater optimization of laboratory workflows.

# SUBSEQUENT EVENTS

### **FDA clearance received for the FilmArray<sup>®</sup> Meningitis/Encephalitis Panel**

On October 8, the FilmArray<sup>®</sup> Meningitis/Encephalitis (ME) Panel received *de novo* clearance from the FDA. With its unique medical value, this panel is the first test to address a critical unmet need for quick and accurate identification of central nervous system infectious agents by utilizing a comprehensive panel to test cerebrospinal fluid (CSF) for the 14 most common pathogens (six bacteria, seven viruses and one yeast) responsible for community acquired meningitis or encephalitis in about an hour. The FilmArray<sup>®</sup> ME Panel should be commercially available in the United States in November and CE-marked shortly after. It can be run on the FilmArray<sup>®</sup> and FilmArray<sup>®</sup> 2.0 multiplex PCR systems.

### 2015 OBJECTIVES

Based on the sales performance for the first nine months of the year, and assuming a flu epidemic of average intensity, bioMérieux is raising its full-year **organic growth objective** to around 6.5%, at constant exchange rates and scope of consolidation. The Company is also pursuing its strategy of innovation and geographic expansion, and actively supporting the launch of its new products, such as VIRTUO<sup>™</sup> and FilmArray<sup>®</sup>. Against this backdrop, bioMérieux confirms the previously announced objective of achieving contributive operating income of between €240 million and €265 million.

# **INVESTOR CALENDAR**

Fourth-quarter sales: January 17, 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 2014 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 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2014, revenues reached €1,698 million with 88% 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 used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the NYSE Euronext Paris stock market (Symbol: BIM - ISIN: FR0010096479).

Corporate website: www.biomerieux.com

Investor website: www.biomerieux-finance.com

### CONTACTS

#### Investor Relations

bioMérieux

Sylvain Morgeau Tel.: +33 (0)4 78 87 22 37 investor.relations@biomerieux.com

#### Media Relations

#### bioMérieux

Aurore Sergeant Tel.: +33 (0)4 78 87 54 75 media@biomerieux.com Image Sept Laurence Heilbronn Tel.: +33 (0)1 53 70 74 64 Iheilbronn@image7.fr

Claire Doligez Tel.: +33 (0)1 53 70 74 48 cdoligez@image7.fr

# APPENDIX: QUARTERLY SALES DATA

Sales by Region - in € millions								
	First quarter		Second quarter		Third quarter			
	2015	2014	2015	2014	2015	2014		
Europe <sup>(1)</sup>	204.0	193.9	210.9	208.5	203.8	192.9		
Americas	176.5	119.6	181.8	130.2	186.0	142.4		
North America	144.7	93.4	147.0	97.4	151.7	108.4		
Latin America	31.8	26.2	34.8	32.8	34.2	33.9		
Asia-Pacific	61.9	53.5	86.9	66.9	81.1	73.1		
Total sales from the regions	442.4	367.0	479.6	405.6	470.9	408.5		
bioTheranostics	4.1	2.1	4.8	2.5	5.1	2.3		
R&D-related revenues	1.4	1.7	0.8	1.8	2.3	1.2		
TOTAL	447.9	370.8	485.3	409.9	478.3	412.0		

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

% Change in Sales by Region							
	First quarter		Second	d quarter	Third quarter		
	As reported	At constant exchange rates and scope of consolidation	As reported	At constant exchange rates and scope of consolidation	As reported	At constant exchange rates and scope of consolidation	
Europe <sup>(1)</sup>	+5.2%	+3.9%	+1.1%	-0.3%	+5.6%	+4.9%	
Americas	+47.7%	+19.6%	+39.7%	+18.2%	+30.6%	+16.5%	
North America	+55.1%	+21.0%	+50.9%	+22.6%	+39.9%	+18.4%	
Latin America	+21.1%	+14.8%	+6.2%	+4.8%	+1.0%	+10.3%	
Asia-Pacific	+15.7%	+0.8%	+29.9%	+11.3%	+10.9%	+0.6%	
Total sales from the regions	+20.5%	+8.6%	+18.3%	+7.6%	+15.3%	+8.1%	
bioTheranostics	+90.1%	+56.6%	+96.3%	+53.3%	+118.2%	+83.0%	
R&D-related revenues							
TOTAL	+20.8%	+8.7%	+18.4%	+7.6%	+16.1%	+8.8%	

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