

# PRESS RELEASE

bioMérieux - Business Review for the Nine Months Ended September 30, 2014

# Solid growth in nine-month sales:

- Up 7.4%, including BioFire and at constant exchange rates
- Up 3.5% at constant exchange rates and scope of consolidation, in line with the full-year target

# The Americas: a significant contribution to the Group's sales performance

Up 7.1% at constant exchange rates and scope of consolidation

China: third-quarter acceleration in clinical application sales

2014 organic sales growth objective maintained

New platform acquired for industrial applications

"In the nine months ended September 30, 2014, bioMérieux's sales grew by 7.4% at constant exchange rates and by 3.5% at constant exchange rates and scope of consolidation," said Chief Executive Officer Alexandre Mérieux. "In line with our full-year target, our sales performance reflects our effectively balanced geographic positions and product portfolio. In addition, during the third quarter, we made further progress on the BioFire integration and launched innovative diagnostic solutions. Our solid growth momentum, combined with our Company's stronger fundamentals, allows us to confirm that we are maintaining our organic sales growth objective for 2014."

Marcy l'Etoile, France - October 22, 2014 - bioMérieux, a world leader in the field of *in vitro* diagnostics, today released its business review for the nine months ended September 30, 2014.

## **SALES**

In the first nine months of 2014, bioMérieux's revenue increased by 7.4% at constant exchange rates, including €45 million in sales from BioFire as from January 16, 2014. Organic growth (at constant exchange rates and scope of consolidation) came to 3.5%. Exchange rate fluctuations, primarily reflecting the rise in the euro against other currencies, resulted in a negative currency effect of €37 million, or 320 bps. In this environment, net sales for the period amounted to €1,193 million, up a reported 4.2% from €1,144 million in the first nine months of 2013.

Analysis of Sales In € millions			
Sales – Nine months ended September 30, 2013	1,144		
Currency effect	-37	- 3.2%	
Organic growth (at constant exchange rates and scope of consolidation)	+41	+ 3.5%	} . 7
Change in the scope of consolidation - Additional sales from BioFire (1)	+45	+ 3.9%	\( \) + 7.
Sales – Nine months ended September 30, 2014	1,193	+ 4.2%	

<sup>&</sup>lt;sup>(1)</sup> BioFire has been consolidated since its acquisition closed on January 16, 2014

In the **third quarter**, sales amounted to €412 million, reflecting year-on-year organic growth of 2.3%. Excluding proceeds from R&D collaborations recognized in revenue for the first time in third-quarter 2013 in an amount of €6 million, organic growth would have represented 3.7% in third-quarter 2014, lifted by a very good September.

Over the **first nine months of 2014**, sales fully benefited from the Company's broadly diversified geographic base. Development accelerated in North America and demand in Western Europe remained satisfactory. These two areas, which account for two-thirds of the Group's business, thereby served as a solid base for expansion that, in particular, offset weak sales in China, notably in industrial applications. Furthermore, China's performance continued to hold back the overall pace of organic growth in emerging markets which, representing 28% of consolidated sales, grew by just 5% year-on-year. At constant exchange rates and scope of consolidation (like-for-like), sales for the first nine months of 2014 are summarized <u>by region</u> as follows:

Sales by Region In € millions	9 months ended Sept. 30, 2014	9 months ended Sept. 30, 2013	Change As reported	Change Like-for-like	Q3 2014	Q3 2013	Change As reported	Change Like-for-like
Europe (1)	595	584	+ 2.4%	+ 2.7%	193	193	+ 1.4%	+ 0.3%
North America (2)	306	257	+ 19.1%	+ 5.9%	111	89	+ 24.1%	+ 6.6%
Latin America	93	96	- 3.1%	+ 10.3%	34	32	+ 6.0%	+ 12.5%
Americas	399	353	+ 13.1%	+ 7.1%	145	121	+ 19.3%	+ 8.2%
Asia-Pacific	194	201	- 3.6%	+ 0.7%	73	70	+ 5.2%	+ 5.2%
Total sales from the Regions	1,188	1,138	+ 4.4%	+ 3.7%	411	384	+ 7.1%	+ 3.7%
R&D-related revenue	5	6	- 28.0%	- 28.3%	1	6	- 81.3%	- 83.3%
TOTAL	1,193	1,144	+ 4.2%	+ 3.5%	412	390	+ 5.7%	+ 2.3%

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

- In the **Europe-Middle East-Africa** region (51% of the consolidated total), sales improved by a significant 2.7% on the first nine months of 2013.
  - Virtually every country in **Western Europe** (43% of the consolidated total) experienced growth during the period, driving a more than 2% increase in revenue. United Kingdom and Germany saw a robust increase in sales. The upturn in business that began early in the year continued in the Southern European countries, generating combined year-on-year growth of about 3%. Lastly, sales were stable in France in an uncertain market.
    - Business was solid in clinical applications, led by instrument sales in microbiology, VIDAS<sup>®</sup> immunoassays and molecular biology. Growth in industrial application sales reflected varying performances across countries. It was driven in particular by TEMPO<sup>®</sup> reagents for the automated enumeration of bacterial flora that may be present in food. This product range was recently expanded with the second-quarter launch of the 10<sup>th</sup> card, TEMPO<sup>®</sup> BC, used for *Bacillus cereus* group enumeration in 24 hours.
  - As previously announced, geopolitical tensions caused a slowdown in third-quarter business in the **Eastern Europe-Middle East-Africa** area. Taking this into account, the area's growth rate came to nearly 6% for the nine-month period.
- The Group's newly created **Americas** region accounts for one third of consolidated revenue. In the first nine months of 2014, sales in the region increased by 7.1%, led by a good third quarter (up 8.2%) in both clinical and industrial applications.
  - In **North America** (25% of the consolidated total), sales climbed by nearly 6% year-on-year. Despite a particularly high basis of comparison, growth in sales accelerated in the third quarter, representing 6.6%.

<sup>(2)</sup> Including €44 million in BioFire sales

In clinical applications, demand for the VIDAS® B.R.A.H.M.S. PCT™ reagent remained very strong. The first FDA-approved test to measure procalcitonin, this solution enables sepsis risk to be assessed in hospitalized emergency care patients in 20 minutes. Its success attests to the high medical value it represents for medical staff and to the flexibility offered by the VIDAS platform®, which is perfectly suited for use in emergency situations. In addition, sales in North America were helped by the installation of a large number of VITEK® MS systems. VITEK® MS is the only mass spectrometry system cleared by the FDA for the routine detection of a comprehensive menu of disease-causing microorganisms and the first system in the VITEK® line to enable detection in minutes.

Industrial application sales accelerated over the third quarter and continued to be led by healthy demand for reagents.

- In Latin America (8% of the consolidated total), the sales growth rate exceeded 10% year-on-year, driven by robust demand in all of the direct distribution countries in the area. In Brazil, sales increased by 8%. In the clinical sector, business in the area continued to be led by reagent sales in the microbiology lines and in the VIDAS<sup>®</sup> immunoassay range. Industrial application sales rose by nearly 13%.
- In the **Asia-Pacific** region (16% of the consolidated total), business was stable year-on-year. Revenue in India continued its rapid ascent, up 19% for the period due mainly to successful sales of the VIDAS<sup>®</sup> range. In the third quarter, sales in China turned upward in clinical applications, delivering growth of nearly 11%. However, business in the country continued to contract, down 2% overall year-on-year, due to the impact of weak industrial application sales. In view of the specific 2014 market environment, the Company took steps to optimize its distribution network and sustainably anchor its development in this strategic country.

In the Asia-Pacific region as a whole, bioMérieux's sales performance in the clinical sector was supported by growth in reagents, including VIDAS® in particular. In industrial applications, slower sales in China continued to weigh on business.

At constant exchange rates and scope of consolidation (like-for-like), sales for the first nine months of 2014 may be analyzed by application as follows:

Sales by Application In € millions	9 months ended Sept. 30, 2014	9 months ended Sept. 30, 2013	Change As reported	Change Like-for-like
Clinical Applications	948	900	+ 5.4%	+ 4.4%
Microbiology	564	570	- 0.9%	+ 2.3%
Immunoassays <sup>(1)</sup>	276	264	+ 4.8%	+ 8.4%
Molecular Biology (2)	96	55	+ 73.5%	+ 7.3%
Other	11	11	+ 1.7%	+ 5.9%
Industrial Applications (3)	240	238	+ 0.8%	+ 1.0%
Total sales from Applications	1,188	1,138	+ 4.4%	+ 3.7%
R&D-related revenue	5	6	- 28.0%	- 28.3%
TOTAL	1,193	1,144	+ 4.2%	+ 3.5%

<sup>(1)</sup> Including VIDAS®, up 9.8%

- In **clinical applications**, growth in business remained solid at 4.4%.
  - **Microbiology** sales were up 2.3%. The third quarter saw sales improve by nearly 5% as the pace of production at the Durham plant began to increase (see the related paragraph under "Third-quarter operating highlights"). Over the first nine months of the year, business was led by the healthy performance of the automated ID/AST line, culture media and microbiology lab automation solutions.

<sup>(2)</sup> Including €38 million in BioFire Diagnostics sales

<sup>(3)</sup> Including €7 million in BioFire Defense sales

- In immunoassays, VIDAS® sales grew by nearly 10% over the period, buoyed by the product range effect stemming from the recent launch of VIDAS® 3, whose installed based stood at more than 400 systems at end-September. Led by demand for reagents and instruments, sales thereby benefited from the successful positioning of VIDAS® in emerging markets, in high medical value assays, especially VIDAS® B.R.A.H.M.S. PCT<sup>TM</sup>, and from the launch of new parameters, including the VIDAS® 25 OH Vitamin D Total test.
- **Molecular biology** reported a more than 7% year-on-year increase in organic sales, thanks to fast growth in the ARGENE<sup>®</sup> line. Including the contribution of BioFire, which has been consolidated from January 16, molecular biology sales grew by more than 70% in the first nine months of the year.
- Industrial applications represent 20% of consolidated sales. Up by just 1% year-on-year, they were held back by weak sales in China, particularly in instruments. Business advanced in all of the other regions, driven by reagent sales. In industrial applications, bioMérieux is able to leverage its broad range of microbiological control solutions to meet the analysis and organization needs of quality control laboratories.
- Sales of reagents and services, which represented 90.6% of the consolidated total, rose by nearly 5% on an organic basis.

## OTHER INFORMATION

#### Net debt

At September 30, 2014, **net debt** stood at €277 million after payment of the BioFire acquisition price in a total amount of €353 million in January 2014. At December 31, 2013, the Company had a net cash position of €25 million.

The Company has €300 million in seven-year bonds, placed with institutional investors in October 2013. Lastly, it has a €350-million syndicated line of credit whose expiration date was extended during the first half to May 20, 2019.

#### THIRD-QUARTER OPERATING HIGHLIGHTS

#### ■ The Durham, NC plant in the United States

The Company is pursuing a broad action plan intended to reinforce the Durham site's quality system and to return to a satisfactory blood culture bottle production situation by the end of 2014. In accordance with this schedule, bioMérieux shifted the newest production line this summer to 24 hours/7 days production (versus 24/5 previously). At the same time, in July, the Company initiated the construction of an additional blood culture bottle production line, which is expected to be effective in the first half of 2017 to provide sufficient production capacity to meet the expected increase in worldwide demand for blood culture bottles in the years to come.

## Ongoing integration of BioFire

Over the eight and a half months from January 16 to September 30, 2014, **BioFire** contributed sales of €45 million, reported in "change in the scope of consolidation" for the period. With the marketing organization still in the start-up phase in the rest of the world, North America accounted for €44 million of the total. At the end of September, BioFire's sales were up 74% on an organic basis, led by the success of FilmArray<sup>®</sup>. In particular, in the third quarter, the syndromic approach of the FilmArray<sup>®</sup> respiratory panel proved to be a highly effective aid in the fight against the enterovirus D68 (EV-D68) outbreak.

During the third quarter, bioMérieux and BioFire made significant progress on the ongoing integration process:

- The FilmArray<sup>®</sup> system is being actively promoted among bioMérieux customers in the United States.
- The R&D strategy has been defined for the coming years, providing a collaborative framework for BioFire and bioMérieux's molecular biology teams.
- In July, the clinical study relating to the use of the FilmArray<sup>®</sup> panel to diagnose meningitis and encephalitis was initiated in various U.S. hospital laboratories. The Company intends to file for FDA approval in 2015 for this fourth high medical value panel.

On the other hand, the legal protest action initiated by a competing company regarding the award of the \$240 million Next Generation Diagnostic System (NGDS) Technology Development contract to BioFire Defense by the U.S. Department of Defense (DoD) was still underway at the end of September and the related work was still on hold. However, in response to the Ebola outbreak in West-Africa, the U.S. Department of Defense has placed new delivery orders for FilmArray® instruments and pouches, as well as for development work required to obtain FDA Emergency Use Authorization (EUA) for a military-use FilmArray® Ebola test. This test was submitted to the FDA for fast-track EUA clearance on October 18. Working in close collaboration with the FDA, BioFire is also preparing a commercial FilmArray® Ebola test for EUA submission so that it can be used as a clinical diagnostic test in hospital laboratories. This submission to the FDA is expected shortly.

## Commercial offer

In the first nine months of the year, bioMérieux enhanced its commercial offer and launched **11 new products**. In particular, in the third quarter:

- bioMérieux announced the CE marking of the new generation BacT/ALERT® system, VIRTUO<sup>TM</sup>. This unique and innovative automated blood culture system for detecting disease-causing microorganisms has extended the BacT/ALERT® range of solutions. Thanks to its increased efficiency, the system will enable laboratories to deliver fast results to clinicians, thereby helping to improve patient care and optimize laboratory productivity. It is now commercially available in target countries that recognize the CE marking. The VIRTUO<sup>TM</sup> launch will concern existing customers in an initial phase, until blood culture bottle supply levels reach satisfactory levels. As of end-September, just two and a half months following the CE marking of VIRTUO<sup>TM</sup>, the commercial launch was proceeding as expected with the installation of the first systems in customer laboratories.
- In addition, bioMérieux announced the launch of **chromID**® **Salmonella Elite**, a new generation culture media solution enabling faster detection of *Salmonella* strains in clinical stool samples. *Salmonella* is one of the most common bacterial causes of diarrhea worldwide and is therefore a major public health concern.
- bioMérieux launched **easySTREAM**<sup>™</sup>, an automated sample preparation station for PCR assays. easySTREAM will enhance the full automation solution that bioMérieux provides to centralized and reference molecular biology laboratories.
- Lastly, for research applications (RUO), bioMérieux has launched the VITEK<sup>™</sup> MS Blood Culture kit, a tool for preparing microorganisms in positive blood culture bottles for direct, rapid identification using the VITEK MS<sup>®</sup> mass spectrometry system.

# **POST-BALANCE SHEET EVENTS**

#### Saint Louis, MO site in the United States: FDA warning letter

On October 13, the Company received a warning letter from the U.S. FDA relating to an inspection in July 2014 of the Company's Saint Louis, MO site that is dedicated to the production of VITEK® cards and certain microbiology instruments. The warning letter pertains to nine deviations from the Quality System Regulations for medical devices (Title 21 Code of Federal Regulations, Part 820) observed by the FDA during the July 2014 inspection. It requests that bioMérieux take corrective measures in particular relating to complaint handling and corrective and preventive action (CAPA) trending. These deviations relate to the site's Quality system management. At this stage, bioMérieux does not anticipate any related product supply issues. bioMérieux will actively collaborate with the FDA to address these concerns to the agency's full satisfaction and plans to provide the requested comprehensive response to the FDA within fifteen business days from receipt of the warning letter.

## Acquisition in industrial microbiology

On October 15, bioMérieux acquired all outstanding shares in Alsace-based **Advencis** (France). This industrial microbiology start-up of seven employees has developed an incubator system for rapidly detecting microbial contaminants in water used in manufacturing, particularly by pharmaceutical companies. The incubator features innovative proprietary imaging technology that enables early detection and enumeration of colonies, prior to their analysis via traditional methods. This easy-to-use modular system is expected to become commercially available in 2015. The acquisition price, including an initial payment and contingent consideration linked to the success of the next development stages, could reach up to a total of €10 million. The system will expand the range of industrial microbiology products that bioMérieux, the leader in this market, provides to its customers.

## **INVESTOR CALENDAR**

Fourth-quarter 2014 sales: January 22, 2015 - 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 2013 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 BIOMERIEUX**

## Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 41 subsidiaries and a large network of distributors. In 2013, revenues reached €1,588 million with 87% 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 market (Symbol: BIM - ISIN: FR0010096479). Corporate website: www.biomerieux.com. Investor website: www.biomerieux-finance.com.

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# **Appendix 1: Quarterly Sales Data**

Sales by Region In € millions										
	1 <sup>st</sup> Quarter		2 <sup>d</sup> Quarter		1 <sup>st</sup> Half		3 <sup>rd</sup> Quarter		9 months ended September 30	
	2014	2013	2014	2013	2014	2013	2014	2013	2014	2013
Europe (1)	193.9	190.7	208.5	200.4	402.4	391.1	193.0	192.6	595.4	583.7
North America	95.5	81.7	99.9	86.1	195.4	167.8	110.8	89.3	306.2	257.1
Latin America	26.2	29.4	32.8	34.6	59.0	64.0	33.9	31.9	92.9	95.9
Americas	121.7	111.1	132.7	120.7	254.4	231.8	144.7	121.2	399.1	353.0
Asia-Pacific	53.5	57.1	66.9	74.2	120.4	131.3	73.1	69.6	193.5	200.9
Sales from the regions	369.1	358.9	408.1	395.3	777.2	754.2	410.8	383.4	1,188.0	1,137.6
R&D revenue (2)	1.7		1.8		3.5		1.2	6.5	4.7	6.5
TOTAL	370.8	358.9	409.9	395.3	780.7	754.2	412.0	389.9	1,192.7	1,144.1

<sup>(1)</sup> Including the Middle East and Africa (2) R&D-related revenue

Change in Sales by Region %										
	1 <sup>st</sup> Quarter		2 <sup>d</sup> Quarter		1 <sup>st</sup> Half		3 <sup>rd</sup> Quarter		9 months ended September 30	
	In Euros	L-f-L <sup>(3)</sup>	In Euros	L-f-L <sup>(3)</sup>	In Euros	L-f-L <sup>(3)</sup>	In Euros	L-f-L (3)	In Euros	L-f-L (3)
Europe (1)	+ 1.6%	+ 2.7%	+ 4.1%	+ 5.0%	+ 2.9%	+ 3.9%	+ 1.4%	+ 0.3%	+ 2.4%	+ 2.7%
North America	+ 16.8%	+ 5.4%	+ 16.1%	+ 5.7%	+ 16.4%	+ 5.6%	+ 24.1%	+ 6.6%	+ 19.1%	+ 5.9%
Latin America	- 10.5%	+ 8.0%	- 5.3%	+ 10.2%	- 7.7%	+ 9.2%	+ 6.0%	+12.5%	- 3.1%	+ 10.3%
Americas	+ 9.6%	+ 6.1%	+ 10.0%	+ 7.0%	+ 9.8%	+ 6.6%	+ 19.3%	+ 8.2%	+ 13.1%	+ 7.1%
Asia-Pacific	- 6.3%	+ 1.9%	- 9.9%	- 4.4%	- 8.3%	- 1.7%	+ 5.2%	+ 5.2%	- 3.6%	+ 0.7%
Sales from the regions	+ 2.3%	+ 3.6%	+ 3.3%	+ 3.9%	+ 3.1%	+ 3.7%	+ 7.1%	+ 3.7%	+ 4.4%	+ 3.7%
R&D revenue (2)							- 81.3%	- 83.3%	- 28.0%	- 28.3%
TOTAL	+ 3.3%	+ 4.1%	+ 3.7%	+ 4.3%	+ 3.5%	+ 4.2%	+ 5.7%	+ 2.3%	+ 4.2%	+ 3.5%

<sup>(1)</sup> Including the Middle East and Africa
(2) R&D-related revenue
(3) L-f-L: like-for-like (at constant exchange rates and scope of consolidation)