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PRESENTATION

Operator

Good day, and welcome to the bioMérieux FY 2023 Results Webcast. Today's conference is being recorded. At this time, I would like to turn the conference over to Mr. Aymeric Fichet. Please go ahead.

Aymeric Fichet

Thanks a lot. Good afternoon, everyone, and thank you for joining us to review the bioMérieux performance for the 2023 full year results. I'm on line with Pierre Boulud, CEO; and Guillaume Bouhours, CFO. Please note that this conference call will include forward-looking statements, which 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 environment, notably those described in the 2022 universal registration document. I also remind you that today's call is being recorded and that a replay will be available on our website, www.biomerieux-finance.com.

I will now hand the call over to Pierre and then we'll open the call to discussion and questions. Pierre, the floor is yours.

Pierre Boulud - *bioMérieux S.A. - CEO*

So hello, everybody. Good to have you all on the phone. So we will share together with you today. I'll start with a few words on our 2023 business performance. Then I will hand over to Guillaume, who will deep dive into the financial performance, and I will close the presentation with 2024 business outlook before we go into the Q&A.

So 2023 highlights. A few elements to share with you. The first one is, as you've seen, we are reporting a sales growth of 6.6% sales growth, ahead on top of a 4% to 6% sales guidance. That is mostly driven with overperformance by a very strong performance of our business, excluding respiratory panel that we guided between 8% and 10%. And at the end of the year, we've managed to achieve 11% sales growth outside of the respiratory panel, so not impacted by COVID epidemiology decrease.

Profitability-wise, we've grown our CEBIT by 2% at constant exchange rates and constant scope, which is actually a performance in the high end of the range, unfortunately impacted by higher-than-expected foreign exchange headwinds in the region of EUR 55 million.

Finally, in 2023, we are very satisfied that beyond this strong commercial performance, we have also been able to launch important innovation that will also support the growth in the next few years, be it SPOTFIRE in the summer of 2023, be it VITEK REVEAL, be it VIDAS KUBE, be it 3P for our industry business and MAESTRIA as a software solution.

So if we go a little bit more granular into the different franchises that we have, as you can see, solid performance of BIOFIRE product range, driven by 3 elements. The first one very strong growth of nonrespiratory panel, plus 24% that is very much driving the performance of BIOFIRE product range and leveraging the installed base that we have, 75% of our customers now use at least 2 panels, which has been increasing in 2023. The second growth driver is installed base. We've managed to expand our installed base by 1,900 instruments, close to 2,000, which is significantly more than we did in 1,500. So an acceleration of new installations and close to 10% of the total installed base.

Final growth driver, internationalization of the sales outside of the U.S. As you know, it's been a key component of our strategy in the last couple of years. We have now close to 40% of the installed base that is installed outside of the U.S. and more close to 27% of our reagent sales outside of the U.S. So 3 growth drivers for BIOFIRE non-RP, installed base growth, internationalization of the sales.

If we move to SPOTFIRE, that has been the entry for bioMérieux to the point-of-care market in 2023. As you know, we believe we have a very competitive solution, 15 minutes time to result, CLIA Waived, 2 panels, 5 plex and 15 plex that allow to maximize the opportunity for the patients to adapt the testing to the patients. We have now 800 instruments installed by the end of the year. We are both an installed base in the point-of-care setting, but also in more hospital classical segments. We have also managed to introduce the product outside of the U.S. So we are now present in 7 countries with first clients in 7 countries.

As you know, in 2023, we've also agreed with McKesson for them to distribute our products in the U.S. And we have filed to the FDA an expansion of the revenue to bring beyond the 5 plex and 15 plex panel for respiratory (inaudible) panel, hopefully, in the next few months.

Next slide relates to microbiology performance. We are -- I am very satisfied with the performance in microbiology, close to 14% sales growth in 2023. Very homogeneous performance in the different regions, very much leveraging the increased awareness around antimicrobial stewardship and the importance of high-quality diagnostics to support the fight against antibiotic resistance. We have a very renewed portfolio of instruments.

We have, as you know, launched VITEK REVEAL and file to the FDA in the U.S. We have launched a new software solution, MAESTRIA that supports our efforts in terms of antimicrobial stewardship. We also aim at complementing our solution with sequencing solutions. As you know, we've entered a R&D project and an equity stage with Oxford Nanopore to bring sequencing solutions into clinical use in the next few years.

Let us -- before last immunoassays slide on immunoassays performance, mostly VIDAS performance. We are back to growth in 2023 with the routine testing that is mostly designed to feed the needs of developing settings. So we've been growing 6% in 2023. We've also launched to support this immunoassay product range, VIDAS KUBE, that is a new platform where every test is actually available on this new platform where it's launched. We have a good commercial launch with close to 400 instruments installed by the end of December 2023.

We've also launched for the developed setting a new parameter, traumatic brain injury. It's approved in Europe. We're filing in the U.S. Unfortunately, as you know, we are still suffering the pressure of procalcitonin that is still decreasing, representing less and less, obviously, in our total sales. And largely compensated by the growth that we have on routine performance.

Last slide, industrial applications. As we've shared with you along the year in 2023, very solid performance, 9% sales growth for our industrial applications, that cover both food and pharma clients, very much driven by one very strong performance in pharma driven by cell and gene therapy, where we have a very high market share for quality control of -- in this industry and significant price increases, Guillaume will further explain on that topic. We've managed to pass significant price increases in those applications that supports the excellent sales performance that we've witnessed in 2023.

And with this, I hand over to Guillaume, who will share with you more details on the financial performance.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

Thank you, Pierre. Hello, everyone. So starting with the sales. Here is a recap of what Pierre presented business by business. So overall, the 6.6%, as Pierre mentioned, above our guidance, which was 4% to 6% and above also on the overall non-RP 11% growth versus 8% to 10% guidance.

So molecular definitely remains our first range of products with 39% of the sales, EUR 1.4 billion of sales. Pierre commented on the 3 subsegments of molecular. By the way, I take this opportunity to mention that we plan now to, let's say, we brought to you externally with these 3 subsegments, with BIOFIRE non-RP and BIOFIRE RP, both being the menu that we have on the TORCH, let's say, equipment, which, of course, we report separately because they have different trend and to report separately the SPOTFIRE as it is a different market segment, the point of care.

On SPOTFIRE, I can mention that the overall revenues in 2023 are EUR 20 million, slightly above EUR 20 million, of which EUR 18 million are reagents which we see as a very good performance in only 6 to 7 months of commercial launch.

Moving to microbiology, Pierre (inaudible). So overall, 34% of the group sales, as you can see. Important to note that part of this record, 14% growth that we are proud of, about 4% is the price increase contribution to pass through inflation to our customers. And the rest is already a very good volume increase of about 10%.

Immunoassay, Pierre commented, overall minus 3% of which minus 2% is the VIDAS main range. Industry 9% overall, with growth that is driven by pharma on the volume part and a very nice performance on the price increase. We've been able to pass through more than 6% to our customers, pretty steady on the pharma and food segments overall.

So with that, I propose to make a few comments by geography, not many details on this slide, but a few comments, maybe color. So Americas overall 4.5%. It's actually a bit lower than that on North America. North America was very dynamic on the microbiology as well as non respiratory, but of course, decrease on the respiratory with the lower flu season and respiratory season, I should say. And of course, the continued decrease of immuno with procalcitonin in the immunoassay portfolio that is specifically strong, about minus 20% in North America. Latin America is a smaller region for us, but definitely a very good growth contributor, super dynamic, over 20% growth overall and really overall the different ranges.

EMEA, 8.5% growth, which includes a super non-RP performance, even significantly above group at 28% growth of non-RP in Europe. I think it's nice to highlight and also double digit in microbiology, which is not so easy in markets where -- that are both mature and where we have already strong positions.

Asia Pacific, 9% growth with, let's say, slightly different trends. China clinical, important to note, excluding Hybiome, and I'll come back in a minute to Hybiome. So I'd say, historical, mainly microbiology business performed very well in a year of recovery of the China market. Now you remember that 2022 was still under lockdown and the disruptions. So this year, recovery we grew more than 15% in China clinical. Japan was down mainly due to its respiratory BIOFIRE exposure, with a lower, of course, COVID respiratory. And India is performing very well, above 20% growth, again, that testifies our strong positioning in emerging India is all ranges, but we can note that in immunoassays is growing in India.

Just to mention a last comment on the geography, U.S. remains, of course, our first market, 43% of group sales. China remains the second market with 8% of group sales, and then countries like France, for example, is 6%.

Now turning to the profit and loss count. So you can read on the slide, let's say, the valuations. And on the last column on the right, the like-for-like changes. So with 16.6% organic growth of sales, you can see that we were able to improve the gross profit on the like-for-like. So actually, the gross profit margin improved by 50 basis points. which is actually factoring the fact that our price increases, of course, stronger on microbiology and industrial applications were good enough to offset a significant part of the inflation. And we also benefited from lower transport costs as the market, especially on sea freight started to normalize.

Looking at SG&A, sales, marketing and G&A, 10% growth overall, including, let's say, one-off impact of EUR 10 million on the MyShare employee ownership plan, which we do every 2 years usually. That is really mainly factoring normalization of the sales and marketing activities, so return to normal trend of events. Customer shows and activities and travel that goes with it, which, of course, we see very positively, because we need to promote with our customers our many product launches and innovations.

R&D, I think the highlights here is mainly in the column of percentage of sales, you see that we maintain a high percentage of sales at 12.5% of sales, very much in line with our bioMérieux target to be significantly above the market and to invest for the long term.

Contributive operating income lands at 2% like-for-like growth, so at constant FX and scope, which is actually above our expectations. So we are pretty pleased that Pierre mentioned already with this result. It's slightly above our expectations. We performed well. What is less positive, I would say, is, of course, an FX impact, which was more headwind than we expected. We ended the year at minus EUR 55 million. I can mention very late in the year with the Argentinian peso, a huge devaluation and I think it was early December after the elections. But there are a number of impacts that are -- just to mention, and we can come back in the Q&A, but some are linked to, let's say, hyperinflation countries like Argentina, like Turkey. Some are also linked to the fact that euro is pretty strong against many currencies, for example, against Chinese renminbi or Japanese yen, much stronger than (inaudible).

So turning to the CEBIT to net income. The very major comment there is actually in the line of amortization of acquired intangibles. As you see this line is pretty heavy with a major impairment that we had to take on the Hybiome acquisition. So for everyone I remind you that Hybiome is a small immunoassay company, about EUR 25 million sales. So I mean in terms of sales and overall contribution, it's pretty small. So an acquisition, we took control back in 2018 and 2019 with minor investors still in the capital.

The company underperformed throughout the COVID period. We were expecting rebound post COVID, and basically, we did not see a rebound in 2023, quite the opposite, and we had to take, let's say, a view on the depreciation of the value. We also decided to -- after a review of strategic options to actually take out some of the minority investors, change the management. So we have a new manager in charge, and we will look at turning around this small Chinese company.

That being said, no major comments on the other line. Net financial expense is slightly improving, of course, thanks to higher interest income as well as lower hedging costs. The effective tax rate, if you exclude the Hybiome impact, which, of course, is a nondeductible impairment or actually very much in line with our historical and guidance around 23.4%, excluding this impact. And net income, of course, is impacted by Hybiome impairment again. But excluding the Hybiome impairment would be down 2%, so let's say, almost stable on the net income, excluding this exceptional one-off.

On the cash flow statement, so the major element here to mention is the working capital, as you can see a major increase on the working capital side that fully comes from inventory. We had several effects in inventory first to reveal some inventory, especially on the BIOFIRE respiratory. You can remember that we ended 2022 or started '23 with extremely low inventory, actually in back order on BIOFIRE RP. So we rebuild inventory, with the growth of non-RP BIOFIRE as well. Of course, we have to follow with inventory as well. And another effect is many, many new product launches such as SPOTFIRE, for which, of course, we need to build inventory to be able to serve our clients in the launches. So quite significant, let's say, investment in the inventory part this year.

The CapEx was very much in line with the expectation, overall, investing in our capacity, mainly for the future, which overall makes free cash flow at EUR 115 million, slightly lower than last year. In the financing activities, you can note the 7% stake in Oxford Nanopore, which [waits] for about EUR 150 million. And so overall, not commenting along the rest. We end up the year with EUR 166 million of net debt, very low leverage of 0.2 and still, I think Pierre mentioned it, very high headroom for investments and M&A, if we need and wish to.

I can make a few comments on the CSR road map. So you remember that this is the road map we announced 2 years ago on 5 pillars. Health, planet, healthcare ecosystem, the way we care for employees and teams and the extended company, overall with this, let's say, roughly 10 KPIs to follow progress. So maybe not to comment on each of them. I'm happy to answer comments. I think the main message is here is that we feel we are on track with our, let's say, more midterm at some time, long term for the greenhouse gas emission, midterm and long-term targets overall on track.

And with that, I hand over back to Pierre on the outlook.

Pierre Boulud - *bioMérieux S.A. - CEO*

Thank you, Guillaume. So moving to 2024, guidance for 2024. So first slide on the growth drivers that we expect to see in 2024. We have 4 of them. The first one is obviously a BIOFIRE product range that we expect to keep growing in 2024, mostly driven by nonrespiratory panels, a very significant success that we've seen in the last 12, 18 months. So we expect to grow around 15%. For respiratory panel, it's obviously related to the impact of the respiratory season. So we plan for a medium respiratory season.

With regards to SPOTFIRE, the second growth driver we expect to ramp up in the U.S. I've talked about international launch, so launching outside of the U.S. And we also expect to see the benefit from having approval on the sore throat panel. So we have a target of EUR 80 million sales in 2024 to be compared with the EUR 20 million that Guillaume was mentioning for 2023.

Microbiology, we plan to keep increasing market share, growing faster than the market. and benefiting from the new instruments that we've launched in the last 2 years, like VITEK MS PRIME and VITEK REVEAL.

Finally, industrial applications, we expect our industry applications to be a growth driver in 2024 with a combination of price effects and the pharma segment growing a little bit faster than food.

So when you put all those growth drivers together, that gives the guidance that we shared with you this morning of 6% to 8% organic, including respiratory for 2024. From a profitability perspective, we expect to grow at constant exchange rates by at least 10% a bit, so that we generate profitable sales growth. Obviously, there is an excellent impact that we estimate at this stage of the year at around EUR 50 million. And finally, we keep investing into manufacturing and the future of bioMérieux with capacity and SPOTFIRE placements, that's 10% to 11% of our expected sales.

Last word before we open for the Q&A. We are very pleased and excited to invite you to Capital Market Day that we plan to organize on April 9. It was an ask from the financial community that we give you a bit more visibility beyond the next few months on our medium-term plans. It's been also -- since I was appointed 1st of July, we've worked together with the management team on refining and stabilizing business perspective for the next few years. So it will be an opportunity for us to gather for me, together with the management team, to share with you both top and bottom line expectations for the years to come. And also an opportunity to showcase the solutions because there will be also a showroom next to the meeting for the presentation. So looking forward to seeing as many of you as possible on April 9 in Paris.

And with this, I think we can close the presentation and open the Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). And we'll go first to Odysseas Manesiotis with Berenberg.

Odysseas Manesiotis - *Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst*

Firstly, could you please explain the details around the recent FDA recalls for the BIOFIRE GI panels that we're yielding for positives and negatives. Have you accounted for any impact from this to your nonrespiratory sales growth guidance?

And secondly, on your EUR 80 million revenue guidance for SPOTFIRE this year, what utilization or revenue per instrument does it assume for instruments you place in 2023? And what are your thoughts on how high this can get when you eventually also had some blood-borne virus panels in there?

Pierre Boulud - *bioMérieux S.A. - CEO*

So let me answer your first question on the GI panel. You're right to say we had a quality concern with our GI panel on 1 out of the 22 targets. So obviously, we take quality matters very seriously. It's a big topic for us. So we are in constant dialogue and discussion with the FDA was notably on these topics. So where do we stand? We've done a field corrective action that is basically around informing customers that on this single target when they have positive results, they need a confirmation actually.

So for you to know, field corrective actions, I mean, real day-to-day business for us, right? We do -- unfortunately, something like 30 filter active actions a year. So this is one of them on all the product ranges. We are very much used to that. We -- again, we take it very seriously. We're obviously investigating the topic. We are informing the clients. Just to clarify, we don't have the customers to return the GI panels to us. We don't have a stop shipment. So we keep shipping the products are just informed we don't see and we don't expect any commercial impact. If any, to be honest, it would be more an acceleration that we are witnessing.

So really business as usual, unfortunately, right? And I mean, when I say business as usual, it may sound a bit strange, right? Obviously, we have a dedicated team working on addressing the challenge, discussing with the FDA. It's a top priority to make sure that we find good corrections to this one parameter that we have, but no major changes and absolutely no change of commercial expectations on our side.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

Your second question was on the SPOTFIRE in 2024 utilization rate. So basically, we try to give you without answering into a detailed model, I would say, our best expectation at this stage and the ability to look at it. That's why we gave you this EUR 20 million or actually EUR 18 million on the reagents for 6 months, of course, 6 months of ramp-up throughout 2023. We were (inaudible) in the U.S. from June. And of course, we ramped up to about 800 instruments in the field from June to December, generating this EUR 18 million. And when we try to -- and of course, you understand, we don't have a lot of, let's say, look back and experience, but when we try to look at further ramp-up of the instruments in 2024 and what it generates in terms of revenues of overall this -- we get to this target of EUR 80 million. Keep in mind, obviously, that it's been mainly revenues in Q1 and Q4. We expect Q2, Q3 to be much lower by a sense of respiratory product at this stage.

Not sure exactly what you target about the blood bone virus, what we -- but maybe to answer more broadly on the pipeline. So at this stage, we have mentioned for SPOTFIRE the RP soft route where we expect approval sometime in 2024 and therefore, being commercial sometime in 2024. Beyond this panel, we would like to actually invite you to the Capital Markets Day where we'll also give more, let's say, visibility on our pipeline for the different products and regions and platforms. So let's share on the April 9.

Odysseas Manesiotis - *Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst*

Understood. Can I squeeze one more in queue. So very quick one. Could you elaborate on how you write the EUR 50 million FX CEBIT impact for 2024? To what extent is there any temporary hedging costs included in that?

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

So yes, with pleasure to elaborate, because it's an important impact. So it's probably important to discuss. Thank you for asking. So first, on the methodology, hedging costs are actually, of course, they are not that big. It's a few millions per year. And it's part of the financial results, so below CEBIT and below EBIT in the financial result line, the hedging costs are there. And they are pretty stable, usually quite stable year-on-year.

No, the impact is mainly an impact of, let's say, conversion and translation of exposure in foreign countries. The very major impacts are, of course, in the most -- in the currencies that have high devaluation. So the top ones are clearly the Argentinian peso again. And again, it's strange because our exposure to Argentina is not that huge, it's a small country for us, but yet the impact in terms of devaluation are so huge that it does impact overall. So Argentina, Turkey, Egypt are among the big devaluation countries.

And on top of that, we have the strength of the euro that is against, let's say, more stable currencies, but euro is being pretty strong. So typically, there are additional impacts against Chinese renminbi, Japanese yen, many of the Latin America currencies. And when you add the EUR 2 million, EUR 3 million for each of those, at the end, it's a big figure, yes.

Operator

We'll go next to Hugo Solvet with BNP Paribas.

Hugo Solvet - *BNP Paribas Exane, Research Division - Research Analyst*

I have 2. First, on margin, should we consider the 50 bps margin improvement at constant exchange rate for 2024. As the floor, can you maybe post debt into context of the 6% to 8% organic growth? And second on industrial applications, how confident are you, you can keep up with a strong growth rate. I mean pricing was about 2/3 of the growth this year? Or should we think about that going forward?

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

On the first one, I'll take that. It's Guillaume. Yes, but definitely, that's why we say more than in our guidance, more than 10% and at least 50 bps. So yes, you rephrased it very well, Hugo, thank you. Yes, we consider it's a floor of our commitment, yes, definitely.

Pierre Boulud - *bioMérieux S.A. - CEO*

And to your second question, Hugo, industrial applications and our confidence to generate 9%, it's actually relatively high. We believe there is -- I mean, it's also the benefit of having a strong market share. We believe we still have pricing power. So we are working on keeping the price increase. As we shared with you in 2023, we had a significant growth in pharma significantly less in food. We are seeing the food volumes to recover in 2024 that would also help to secure the 9% target that we have. So I mean it's -- I'm not going to say it's an easy target because the teams would hate me. But it's -- we are confident in our capacity to grow at that pace in 2024 for industrial applications. Okay. Does that answer your question?

Hugo Solvet - *BNP Paribas Exane, Research Division - Research Analyst*

Yes, it does. Just going back on the first question, should growth be 8% or above? Should we think about margin up 100 basis points or higher. And longer term, probably this -- the growth that we have this year 6% to 8% and margin improving 50 basis points given all of the accelerating moving parts in the portfolio and leverage should we think about 2024 guidance as a base from which you should accelerate going forward?

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

It's a very good question, and we believe it's a very good topic as well. We definitely want to address the profitability improvement. It's definitely a topic for you and for us. And I would -- again, I think it's one of the key topics, not the only one. One of the key topics, we want to take more time to explain at the Capital Markets Day, how we see that over slightly longer period in 1 year and give you more visibility in the medium term on our ambition to improve margins step by step.

Operator

We'll go next to Aisyah Noor with Morgan Stanley.

Aisyah Noor - Morgan Stanley, Research Division - Equity Analyst

I have 2, please. The first one is on the 2024 guidance for RP sales, which you as mentioned in the press release to slightly slow down in the year. Could you define what slightly slowdown means is that less positive? Or is it negative? And could you elaborate the drivers of the slowdown and how much you've assumed from a lower flu season? How much from negative pricing? And I guess to what extent does this outlook embed some competitive headwinds from 4, possibly 5 newcomers in the multiplex market in the U.S. this year? And then I'll leave that for the next one.

Guillaume Bouhours - bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO

Yes. Aisyah, thank you for the question. So yes, the slight slowdown is actually a decrease in our guidance overall. So to make a round figure, it's, let's say, around minus 5%. And it includes definitely when we say medium flu season, we consider that the Q4 2023 was above 1 million. That's why we mentioned that we beat at the end of the year, our guidance with 6.6% instead of maybe 4% to 6%. So quite strong. And on top of that, yes, it does include a very slight price pressure, low single digit, but slight price pressure 1% to 2% is included in our view for (inaudible).

Aisyah Noor - Morgan Stanley, Research Division - Equity Analyst

Okay. And then the second one was just on the -- you mentioned in the press release, an investment in SpinChip Diagnostics. If you could elaborate what is the value of this investment? And could you talk a bit about the competitive strengths of this technology versus existing point-of-care immuno platforms in the market? As I understand this market is quite saturated, at least on the singleplex side.

Pierre Boulud - bioMérieux S.A. - CEO

Yes. Thank you for the question. I can take it. So we've made an investment of EUR 10 million into this Norwegian company. It's a start-up. They have -- to your point, it's a market where there are lots of solutions available. What we're seeing in SpinChip is a very interesting technology that allows to give very good level of performance, very sensitive results especially for cardiac markers. So we feel they have a promising technology. That's the reason why we invested in them.

The rationale -- strategic rationale for us is, as you understand, we've entered now this point-of-care market with SPOTFIRE. So we are very active at looking for opportunities to complement our portfolio in the point-of-care setting. And definitely, beyond molecular point-of-care solution. We believe that we could nicely complement our portfolio with obviously well differentiated immunoassays point-of-care solution. So that's a strategic rationale for the investment.

Guillaume Bouhours - bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO

Maybe to take some questions. I take 1 or 2 from the line, and thank you for also raising questions by writing. There's one about the effort on inventories in '23, which we expect in '24 and '25. Actually, we give some idea on the CapEx, but we don't give really guidance on the inventory or the cash flow. We can see if that's something we can do on Capital Markets, let's see, but no specific guidance today on this. You want to add something to that?

Pierre Boulud - bioMérieux S.A. - CEO

Yes. I mean what's for sure is that in 2023, we rebuild the stock that we didn't have at the end of 2022. So there was a as Guillaume was saying, in 2023, there is a negative element, which we were in back order, especially on BIOFIRE. And we've rebuilt the stock to be able to meet the demand during the respiratory season, which by the way we did, we are not in back order anymore. So this rebuilding of stock is not going to happen twice. But we don't give specific guidance on cash flows just to reassure that the rebuilding of stock is not going to happen every year, hopefully.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

There's a question on the split by country of SPOTFIRE fire or the installed base. It's actually vastly U.S. Yes, more than 90%. We are present again in 7 countries, but which the second is Japan.

Pierre Boulud - *bioMérieux S.A. - CEO*

The second biggest country is Japan.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

But really far from the U.S. base. Maybe taking questions online.

Operator

And we'll go next to Maja Pataki with Kepler.

Maja Pataki - *Kepler Cheuvreux, Research Division - Head of Med Tech Devices Sector*

First, quickly on SPOTFIRE, can you elaborate a bit on the reagents, was it mainly the low plex to sort of 5 plex panel? Or did you also see demand for the 15 plex? Can you provide us an update where you stand with regards to the reimbursement for the 15 plex?

And then on BIOFIRE, the guidance that you're providing on the non-respi, so you're looking for a marked slowdown in non-respi sales growth. Is that related to the expectation that some of your competitors are going to be present in the U.S. market with non-respi panels? Or what is the reason why you're seeing this dramatic slowdown? And how much? Is it volume slowdown? And how much is pricing impacting there?

Pierre Boulud - *bioMérieux S.A. - CEO*

I take your 3 questions. So SPOTFIRE reagents, thank you for raising it. It's a good question. Actually, the -- it's early days, right, because we've been in the market for just a few months, and we've seen the beginning of the respiratory season. By the end of 2023, it was 60% of the volumes with the 5 plex panel. And 40% for the year with the 15 plex panel, which is sold at a higher price. So for us, it was -- it shows in a way the value of having the combination of 5 plex and 15 plex.

It also shows that obviously, the reimbursement is less convenient to your second question on 15 plex and 5 plex, but it shows that the medical value of the fixed implex is proving good enough to justify the use by the clinicians.

The third question relates to the evolution of non-RP, yes, I mean, we guide for 15%, while we've experienced 24%. We don't expect price decrease more on the contrary, but we are basically. We don't -- we kind of factor in, yes, of course, a little bit of competitive pressure, but it's more that the market -- we don't expect the market to keep expanding 25% every year, right? So in French, we say the trees don't grow to the sky.

So, yes, we expect that growth rates, even though we are working on it to decline a little bit, but mostly driven by the fact that the market capacity to grow at that pace is going to be challenged at some point. So that's the rationale for this 24% moving into 15%.

Maja Pataki - *Kepler Cheuvreux, Research Division - Head of Med Tech Devices Sector*

Okay. Can I just double check what you mean with less favorable on the 15-plex. It doesn't mean you don't have the reimbursement yet. Is that what you're saying here? And if that's the case, when do you expect the reimbursement to come through? And on your commentary that there is not a price increase from the non respi, do you anticipate similar pricing pressure like you mentioned for the respi side of the business?

Pierre Boulud - *bioMérieux S.A. - CEO*

So on your first follow-up question that the reimbursement, the 15 plex panel to make it simple, it reimburse the very same way for the clinicians, the way BIOFIRE RP panel is reimbursed. So we have limitations and conditions with that related to 15 plex, but that apply the very same way. So it is reimbursed, but definitely in a point-of-care setting, it's less convenient. For instance, you have HMOs that limit the use if you're far away from the hospital or for immuno-depressed patients. So there are conditions that are depend by payer that limit a little bit the reimbursement conditions for the 15 plex. But the 15 plex is reimbursed. It's a coverage matter. It depends on the patient profile and yes, the circumstances of the testing being done.

The 5 flex panel, as you know, between 3 and 5 plex, the conditions of reimbursements and the coverage is much higher, so that makes it significantly easier to use 5 plex panel for the clinicians.

Now for the -- we don't anticipate. We believe with regards to the pricing evolution for the non-RP we don't anticipate price pressure. We don't believe there will be any. We believe we have very competitive solutions. And at this stage, we don't see any price pressure. So this is not in the 24% to 15% evolution.

Operator

We'll go next to Shubhangi Gupta with HSBC.

Shubhangi Gupta - *HSBC, Research Division - Equity Analyst*

I have 3 questions. Yes. So first on the industrial solution, what is the level of price increases we should expect in 2024? Second, on your -- for your FY '24 outlook, have you included any impact of volume-based procurement related ASP cuts in your guidance? And are you seeing any price cuts in China? And then third, on the U.S. market. So a lot of competitors are also present at a point-of-care testing. So do you see any scope of expansion into retail pharmacy clinics for diagnostic testing?

Pierre Boulud - *bioMérieux S.A. - CEO*

I'll start with the second one, which relates to a volume-based pricing tenders in China. So our business is not impacted in 2024. It's a significant share of our sales is done in microbiology, where there is no volume-based pricing. And the business that is in immunoassays is not impacted either, because it's mostly procalcitonin that is not part of the scope of volume-based pricing.

So it doesn't mean we are immune to price cuts in China. But so far, for 2024, we don't expect any negative pricing impact on our business for bioMérieux in China. Pricing evolution for industrial applications, I don't know if we give any color on that. So I'm betting the body language of Guillaume say no. We don't give color. It's a combination of volume and price. We don't expect as much as what we had in 2023. That was 6%, if my collection is correct. So not as much as 6%, but still significant, and that helps with the 9% target that we have.

Your third question, I'm not sure I got it actually. Do you mind saying it again.

Shubhangi Gupta - HSBC, Research Division - Equity Analyst

Yes, yes, sure. For my third question. So there's a lot of competition in point-of-care testing in the U.S., which is the major market for point of care right now. So do you also see expansion of this diagnostic testing in retail pharmacy clinics like of CVS and Walgreens?

Pierre Boulud - bioMérieux S.A. - CEO

So -- yes, got you. Very good question. It's a very good question again. At this stage, we don't have any of that into our target for -- which is EUR 80 million from 2024. It may be an opportunity. But at this stage, this is not put into calculations, but obviously, it's a business opportunity. If and when retail pharmacies decided to incorporate the diagnostic solution point of care, and we would be delighted to have the discussions with them with SPOTFIRE. We have very high-level discussions, nothing concrete and specific at this moment.

Guillaume Bouhours - bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO

Thank you. Maybe taking a few questions from the chat. So we have one question on Specific Diagnostics loss in 2023. We had guided on EUR 20 million, EUR 25 million when we acquired. And the question, will it be breakeven in 2024. So this -- and actually, a related question on the performance in 2023.

So first thing to say that definitely, the ramp-up in Europe is slower than we expected. It takes more, let's say, effort to convince and to get, let's say, yes, the sales ramp-up. And on top of that, in the U.S., we are still, as you know, in the FDA review process, we are confident, but we are later than we expected EUR 18 million 2 years ago, 2 years ago at the acquisition time.

So definitely, this delay on the European ramp-up and U.S. registration filing approval make the revenues lower in '23. Therefore, the loss is definitely higher than the 2025. It's a bit overall delayed. And the breakeven as well that we mentioned in '24 will be delayed. We are still very confident on the value of the platform on its, let's say, commercial potential, but definitely in a delayed time line.

Pierre Boulud - bioMérieux S.A. - CEO

And maybe to complement Guillaume's answer on VITEK REVEAL. You have to understand that now VITEK REVEAL and the Specific Diagnostics teams are fully integrated into bioMérieux. So we actually -- for instance, when we look at the investments in R&D that are at [12.4%, 12.5%]. They fully integrates VITEK REVEAL, Specific Diagnostics R&D investments. So we relocate the R&D investments to make sure that we cover the needs for Specific Diagnostics, but reduce the cost of the investment in R&D and some other areas.

So at some point, looking at VITEK or Specific Diagnostics as a single entity within bioMérieux won't make much sense. The microbiology teams sell VITEK REVEAL. R&D teams in microbiology work on VITEK REVEAL. So it's now part of the solution, part of the integrated solution that we propose in the field of microbiology, and that's how we look at it moving forward.

Guillaume Bouhours - bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO

There are two questions on the Oxford Nanopore about situation seems to depend -- I'm not sure what you mean. Maybe it's the share price or and you say concern about the investment. More importantly than related, there's a question on, do we expect to increase our stake there are standstill agreements. So maybe if we can complement. But clearly, on the stake, we know, we took 7%. We don't expect it to reincrease. We have, as you know, an R&D agreement. We have regular contacts with the CEO, CFO and R&D levels to follow both the R&D partnership as well as the overall Oxford, let's say, institution as we are one of the main, let's say, investors.

Pierre Boulud - *bioMérieux S.A. - CEO*

Yes, and maybe to bring a little bit of color to it. We are very happy with the quality of the relationship we have with Oxford Nanopore. We are very excited by the technology and it's a long-term investment. So the very recent share price evolution for us is not a challenge, because we invested in Oxford Nanopore with a more medium- to long-term perspective. So no specific concern on our side.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

And another question on the chat is about the EUR 400 million target for SPOTFIRE. So definitely, yes, we do confirm. We'll give you more color with last year and this year, let's say, guidance. And we believe this is on track for the EUR 400 million, 2027 is still a long way, but definitely on track at this stage at this early stage for this target.

There's an additional question on the pricing pressure on BIOFIRE, so not SPOTFIRE but BIOFIRE. We mentioned earlier, minus 1%, minus 2% on the RP. So we -- that's what we -- yes, sorry, we said that for '24, but that's what we saw in '23. So yes, it's what we saw and what we expect additionally in '24. It's triggered by -- I mean, if I'm not really the direct competition of the direct syndromic, (inaudible), GenMark, et cetera, but also the indirect competition of low plex and the pressure from, let's say, customers also to manage their own cost post-COVID probably with more focus on this part, post-COVID. More questions from the phone, maybe?

Operator

Yes. We'll go next to Chris Ganet with ODDO.

Christophe-Raphael Ganet - *ODDO BHF Corporate & Markets, Research Division - Head of Equity Research*

Can you hear me?

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

Yes, we can.

Christophe-Raphael Ganet - *ODDO BHF Corporate & Markets, Research Division - Head of Equity Research*

Actually 2. One is on the point-of-care situation and environment. I'd like to hear you about the reaction, potential reaction of Cepheid on the field? Have you seen any change in terms of strategy, in terms of keeping their clients in terms of client policy? That's the first one.

And the second one is on SPOTFIRE. Can you help us understand the utilization as well concerning, for example, the reorders, the pace of reorders, the potential feedback, notably in terms of lack of panels, if there is, is there a specific disadvantage now that they are using it comparing all the machines? Do they see a specific reason to give back the machine or -- and about the pace of placements probably giving us some contrast with the 400 systems placed during the last quarter?

Pierre Boulud - *bioMérieux S.A. - CEO*

Okay. So I take it competitive situation. Do we see any specific reaction from Cepheid. Obviously, probably more of a better question for (inaudible) from Danaher. They have a remarkable position in this field of point of care. They're a very strong competitor. So we don't take them lightly. Beyond Cepheid, we have also Roche with Liat. We have also Abbott with ID NOW. So we are very much trying to be -- we believe we are very competitive. Obviously, every player is acting in its own different way, but no specific competitive intelligence to share at this stage, which also depends on the

market. So no specific reaction. If any, we are not only competing against Cepheid, we also have Roche and Abbott that are in this market of point-of-care testing.

The other question is to have a little bit of qualitative feedback (inaudible) properly your question on first clients for SPOTFIRE. It's actually very positive so far. We don't have any clients that I'm aware of returning the instruments. They are using the reagents. Like the 15 minutes, the Time to Result, the line ease of use. What we're also hearing is the lag, the double panel, 5 plex and 15 plex.

What else can I share? Menu, it's a good question. In point of care, I mean, the respiratory and sore throat are really the big element. So the menu is obviously important, and we plan to enrich the menu that is available on SPOTFIRE. But the 2 big components where we need to be present are really respiratory and sore throat. So what we expect is that in 2024, with hopefully, the approval of the sore throat panel in the U.S. will be in a very strong position to be very competitive in the market.

We don't give guidance on placements, new instruments.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

As we are talking about SPOTFIRE. There's a question on the chart on the split between outpatient approach in the hospitals.

Pierre Boulud - *bioMérieux S.A. - CEO*

So I can give that feedback. So again, early days, but what we're seeing today is 80% of the instruments installed are in a point of care setting and 20% in hospital settings. So as we expected, there is an opportunity for point-of-care solution into IDNs and hospitals and it's proving to be correct. And we are starting to see, it's early days, but installations. You have to understand that in this specific segment, the purchasing process takes a little bit more time, because you go to a full purchasing process with the finance and so on and so forth. But the opportunities are also bigger, because when they buy, they buy for multiple installations at once. So we're starting to see good traction also on this segment. But today, if we look at our installations, they are 80% into point-of-care setting.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

I'll take the additional question on the FX, sorry, back to that. But thank you for the question, of course. So the question mentions that there are, of course, big differences that are very visible on the stock rates of Argentinian peso, Turkish lira and is not mentioned in the question, but I can add the Egyptian pound. But that it's not so visible that there is a headwind for other currencies.

Just to mention that our policy is to hedge the -- for 1 year, the currencies that are -- that we can hedge, so not the most volatile, which means that we hedge in Q4 for the year after. So when we look at it, it's actually the difference of, let's say, throughout Q4, so let's say, average Q4 rates to make it simple, rates or forward rates compared to average Q4 the year after. And when you do that, it's a reality that renminbi for China, yen for Japan, and then I mentioned South America, so Colombia, Mexico, et cetera, are the currency headwinds.

And when you add, I mentioned earlier, EUR 1 million, 2 million, 3 million for each of these currencies, at the end, it adds up to the big amount of Argentina, Turkey, Egypt to this, let's say, around and of course, it's -- so an estimate with the community at this stage of the year as the currencies move one direction or the other, it's the estimate that we have at this stage of the year.

Pierre Boulud - *bioMérieux S.A. - CEO*

There is one back to SPOTFIRE. There is a question on the chat on risk of cannibalization between BIOFIRE and SPOTFIRE. So the answer is no. Very limited. We are super excited with the sales perspective for SPOTFIRE because there is very limited cannibalization. So as I said, 80% of installation in point-of-care setting. So by (inaudible), 0 competition with BIOFIRE. And even when we sell to IDNs or integrated distribution networks, what

we're seeing is -- back to the earlier question, we're actually -- the SPOTFIRE purchasing process is more against Cepheid, Liat, ID NOW than against the BIOFIRE, they use SPOTFIRE for frontline testing, and they keep BIOFIRE and TORCH for second-line testing. So we are actually seeing more of a synergistic approach than cannibalization by being capable to market both SPOTFIRE and BIOFIRE.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

And we can take additional questions online. There are a few additional.

Operator

Yes, we'll go to Hugo Solvet with BNP Paribas.

Hugo Solvet - *BNP Paribas Exane, Research Division - Research Analyst*

Actually, I have two. Setting back on your comments from a slower growth traction of (inaudible) do you see, on the other hand, pockets of upside risk to other platforms that could help offset that longer term?

And second, you mentioned beyond that you have underutilized balance sheet. So what's your thinking around M&A? Maybe you can expand a bit on large acquisitions versus probably smaller bolt-on deals that you've historically been doing.

Pierre Boulud - *bioMérieux S.A. - CEO*

So Specific REVEAL, yes, we're seeing a bit of a slower-than-expected sales growth in Europe, mostly related actually to -- there is a very strong medical need, very strong technical validation by the hospitals and financing challenging, because we are basically, as we did with BIOFIRE. We are creating, generating a new market segment with fast AST that today is not necessarily into the tenders and the budget from the labs. So we are working on that. We are very confident, it will bring a ton of value to bioMérieux and it's a long and complicated process as we experienced, by the way, with syndromic testing with BIOFIRE.

The second element is that relates to Specific REVEAL is we're actually seeing lately the halo impact on the rest of our microbiology offering, because definitely, we are bringing innovation. So it's rejuvenates the interest for the entire suite of microbiology solution that we have, be it VIRTUO. We have very strong growth in hemoculture, be it VITEK very strong growth in ID/AST count, be it VITEK MS PRIME. So we -- it's obviously complicated to measure, right, but it contributes to the very strong performance that we're seeing in microbiology. And we don't see, to your question, any potential risk on downside more of the contrary actually, on the rest of the microbiology offering.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

And for the -- your second question, Hugo, which is really about M&A, pretty simple. We very much like to share in the Capital Markets Day or let's say our philosophy or the way we could look at it. I don't expect that we announced a big acquisition on April 9. That's not the topic. But definitely, to share how we see using our further ways we could use our balance sheet and clearly invest for the growth of bioMérieux in the future. These will be among topics on April 9.

Pierre Boulud - *bioMérieux S.A. - CEO*

Any more questions on the phone?

Operator

At this time, there are no further questions.

Pierre Boulud - *bioMérieux S.A. - CEO*

Okay. So I think we are anyway running out of time. So thank you, everybody, for very interactive session. Looking forward to hopefully seeing or talking to you on April 9 for the Capital Market Day, and thank you very much.

Guillaume Bouhours - *bioMérieux S.A. - Executive VP of Purchasing and Information Systems & CFO*

Thank you.

Operator

This does conclude today's conference. We thank you for your participation.

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