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PRESENTATION

Operator

Good day, and welcome to the bioMérieux Full Year 2021 Financial Results. Today's call is being recorded. At this time, I would like to turn the conference over to Franck Admant. Please go ahead.

Franck Admant - *bioMérieux S.A. - Director of IR*

Thank you. Good day, everyone, and thank you for joining us to review bioMérieux performance for 2021 and our objective for 2022. Before leaving the floor to Alexandre Merieux, Chairman and CEO; and Guillaume Bouhours, CFO, I will just make a very short introduction to provide you with a couple of information. First of all, our press release was published this morning at 7 a.m. You can find it on the home page of our website.

In addition, note that the slide of this meeting will be available also on the home page, and you can download it shortly after the webcast. From here to the end of the meeting, the webcast and the call will be available in replay on our website.

Now going to the presentation contains after reviewing our 2021 performance and 2022 objectives, where we hold the Q&A session. Questions can come from the conference call and from the chat of the webcast. If you wish to ask a question, please make sure to identify yourself, name and company. The very last word before starting the presentation, and we will not read the slide, which is currently projected, but I recommend you to take note of its contents, that to remind the usual disclaimer about the forward-looking statements.

Now I hand the call over to Alexandre Merieux.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Thank you. Hello, everyone. Good day, good morning, good afternoon for some of you. So let's start with the review of our '21 activity. So we'll start by saying that 2021 has been for bioMérieux after 2 years of COVID, again, a year of remarkable performance. I believe we developed strong performance, both in terms of sales growth. The organic growth was double digit at plus 10.5%. Strong financial performance also as we reached EUR 801 million in terms of contributive EBIT, close to 24% of the sales and also worth noting also that we are a debt-free company since we have a free cash flow generation of more than EUR 500 million.

I would say also that during this last year, also, we have been able to improve [reagents] also corporate social responsibility vision and road map. And as you will see also a bit further, we have a solid pipeline of new solutions to be launched and also as we hope that the world is going into an endemic phase of the COVID, we believe we are well positioned to address this endemicity and also all the needs related to the fight against AMR, standing for antimicrobial resistance.

So maybe I will start with the performance of [key win], which is BIOFIRE. As you can see, we have displayed that here, organic growth of plus 14%. Important to note that during the COVID time period, we doubled the installed base of instrument. Now we reach around 22,000 units being sold

and placed. Worth mentioning also that we had a good growth on the respiratory panel at plus 14%, but that the nonrespiratory, the gastrointestinal panel, meningitis panel, pneumonia panel and BCID panel also have displayed a nice growth in terms of region at plus 35%. So solid growth this year. The fact that Omicron was hitting the U.S. and the rest of the world in Q4, so obviously, we've seen impact. We had strong demand signals in Q4 for RP panels.

Maybe the next one, microbiology, which is also core to us. I believe this is being also nice -- a solid performance. As we have both our classic system, I would say, just a [VITEK BacT/ALERT] growing well in terms of growth, in terms of the placement also. We have been able to leverage our offer across the portfolio. We launched in Europe to get the key marketing for the VITEK MS PRIME, which is a promising system, and we expect to have the VITEK MS PRIME to be FDA cleared in 2022.

Regarding immunoassay, we had a growth of 8% last year. I would say, with 2 different aspects, some tailwinds from the pandemic. Of course, we benefited from the good performance of our SARS-CoV-2 serology test. Also, we had a stronger demand for a specific test linked to the infectious cases linked to COVID, but we have also some headwinds, and we could continue to have a competitive pressure on the PCT, mainly in the U.S. And also, we had to -- we had the Field Corrective Action in Q4, which is now solved, but which impacted us in Q4. Otherwise, also, we made good progress launching important new products on the VIDAS, such as the one at TB-IGRA for tuberculosis and NEPHROCHECK for acute kidney injury and also Dengue, the first one for arboviruses.

Looking at the industrial application, which also had a solid performance, double-digit growth for the industry business in 2021 after a more difficult 2020 linked to the different lockdown. And as you know, we are active in the field of health care and also in the field of [food testing] and quality control. And I would say, in both segments, we enjoyed a good growth pushed by the -- our offering, of course, and the fact that the biopharma, biomanufacturing market is moving fast, and our Q3 solution are well adapted.

And in the field of food testing, we have a very strong momentum with our solutions and many our solutions linked to molecular technologies such as GENE-UP and Invisible Sentinel.

With this short review of '21, I will now leave the floor to Guillaume to guide us on the performance.

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

Thank you. Hello, everyone. So let's review our financial and operating performance. So here, you have the summary of what Alexandre has already presented, how the split of the organic growth by major range.

So you see actually that all of our major ranges performed extremely well in '21. Molecular is #1 with 38% of sales. Overall, molecular is plus 8%. Inside molecular, Alexandre presented BIOFIRE overall plus 14%. I have to mention that the nonsyndromic molecular was actually down, and we had reported on that during the year. After an exceptional 2020, our R-GENE NucliSENS ranges were overall down 40% in '21. So basically coming back to more pre-pandemic levels or closer to. Microbiology, plus 13%, immunoassays plus 8% and industry plus 10% as presented by Alexandre. So really balanced growth between clinical applications plus 10.5% and industry plus 10.2%.

Now looking at the same, so organic growth by geography. Americas remains, of course, our first region with almost half of the group sales at EUR 1.7 billion. North America was up 8% with a strong push from syndromic molecular as well as microbiology, slightly offset by PCT pressure, as Alexandre mentioned already. We can notice a remarkable growth of 19% in Latin America, well balanced in overall inside the region in different countries.

EMEA, of course, our second region, up 11%. Europe was pushed by or driven by syndromic molecular, but also a good growth of the microbiology. Immunoassay recovery from low in 2020 and industry as well. The Middle East and Africa region was up double digits. So overall, excellent performance there as well.

In Asia Pacific, plus 16%. There, I would like to mention our very strong success in Japan since the introduction of BIOFIRE at the end of 2019. And so the success that we had mentioned in '20 was pursued and accelerated in '21, so excellent there. Steady growth in India and Southeast Asia.

And overall, China suffered a bit in Q4 because we have a lot of immunoassay business there from the Field Corrective Action. But still, overall during the year is a bit more than the mid-digit growth, so quite good growth in China.

Now moving to the P&L. So overall, the 10% organic growth turns into an 8% reported growth with some negative foreign exchange, especially on the dollar, on the sales. As you can see, gross profit improved from 56% to 58%. So that's a significant improvement linked first to volumes, volume increase, of course, and a better absorption of fixed costs at our gross profit, gross margin. And second, to the mix with a positive mix effect. You have seen that the reagents of BIOFIRE in terms of growth are plus 18% in terms of organic. So obviously, higher than the rest.

Cost below gross profit. So SG&A is overall a 5% like-for-like growth, but we have to mention that this is on the low level of spend as we have said for the last 2 years, actually. 2020 and 2021 due to COVID were very low on [Congress], marketing, travel and a number of these, let's say, commercial topics.

R&D was overall on a like-for-like basis, flat after we have to announce in 2020, some COVID-related product development cost and performance share -- phantom share of the costs that were inflating the 2020 base, not only in R&D, but in a number of lines.

So overall, contributive operating income, our main KPI at a record level of EUR 800 million, almost 24% of sales and up 36% on a like-for-like basis. Just to mention that on CEBIT, on the contributive operating income, the foreign exchange effect was also negative, minus EUR 33 million, in line with our, let's say, expectations.

I move now to the P&L below contributive EBIT. So still, let's say, the flat recurring cost of acquisition or the PPA of the BIOFIRE acquisition over [15 years], that is flat at EUR 70 million. This year, in '21, we have no nonrecurring expenses versus 2020, where we had a lot of exceptional solidarity actions and the first contribution to our corporate endowment fund of bioMerieux that all -- we made the EUR 42 million last year, as a reminder. Something to note is major improvements in the net financial expense, moving to minus 10%. Of course, we will see in a minute that our net debt position moved to a net cash position that helps, but also the refinancing that we did on that in June 2020 helps improve the situation and lower the cost.

Income tax is slightly decreasing at 22.7% effective tax rate. We benefit from a lower French corporate income tax that moved from 32% to 28% and also to -- from a stronger U.S. profit base. So overall, net income book share EUR 600 million, up 49%, EUR 5.06 EPS that will lead to a proposal at the AGM of dividend of EUR 0.85 per share, which represents a payout ratio of 17%.

If we look together at our cash flow statement, for the first time, our EBITDA was above EUR 1 billion, of course, in line with the EBIT improvement.

Working capital was actually a consumption of EUR 38 million of cash. Inventory increased by EUR 62 million. You remember that we were very low on inventory of BIOFIRE, actually in backorder at the end of 2020. So we actually especially increased raw material and finished products for the BIOFIRE products. Payables and receivables, overall, very much in line with our activities and some improvements of the days of receivables.

And important to note, the last part of the famous phantom share plan. For everyone, this is our U.S. team retention plan that was bonus long-term incentive plan based on the share price of [fair] value. So we paid it fully the last part of it in March, April. So that's, of course, a cash out in terms of working capital.

CapEx, I will show you some details in a minute, but pretty solid at 9% of sales, EUR 290 million. And so overall, leading to a free cash flow that is a record for us at EUR 540 million, and that leads even after a few small acquisitions and the dividends at a strong, strong improvement of our net debt actually becoming net cash position. So now a net cash position of EUR 340 million, including the IFRS 16, which is about EUR 96 million.

Just a few pictures. I think it's nice to share with you where we invest. So some of the main CapEx of 2021. We are not the only ones, of course. But on the top left, you have the office -- the new office building in Salt Lake City just right next to the new plant that we opened the year before. That is finished and that actually our team moved in, in November.

On the top right, you have a picture of all the, let's say, additional capacity and also progressive automation of BIOFIRE manufacturing that we're investing in. And on the bottom left and right, you have 2 buildings that are almost next to each other in Suzhou in China. One is for bioMerieux Blood Culture business produced in China for China and the other one is for Hybiome, our immunoassay business that we took control of, remember 3 years ago, and which is building its new site, manufacturing and all functions.

And with that, I hand over back to Alexandre for our '22 priorities.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Thank you, Guillaume. So let's start -- let's switch to our '22 priorities and outlook, and we'll focus a bit on the -- on 2 key focus for it, which is the fight against antimicrobial resistance, also syndromic testing. We will give you also some details around the innovation, R&D road map and new product launches. We talk about CSR. And of course, we give the guidance for 2022.

So let's start with antimicrobial stewardship, which as you know, is really core to bioMerieux. It's in our DNA to be present and to fight this important threat. You might have seen that the Lancet study has shown that in 2019, in fact, about 1.3 million of deaths linked to AMR. Some call it the silence pandemic. This is really where bioMerieux is active. And we have seen during this last 2 years a strong recognition of value of diagnostics. And diagnostics also will be key to fight against AMR, knowing that we are lacking new antibiotics, but there will be -- a diagnostic will be a key element of the fight against AMR. So of course, we have R&D. We have a commercial relationship or co-distribution of specific data. But we keep on investing in that space. And also we'll develop some priorities for '22 linked to medical education, first to train and inform all the different health care providers around the world.

Investment also in medical and economical outcome studies to support the adoption of the access of diagnostics. And also partnerships with selected centers of excellence as between to share our AMS best practices around the world.

The second topic, which is important for us, of course, you know the success we have and the leadership we have with syndromic testing with BIOFIRE, we'll keep on FILMARRAY, we'll keep on expanding the menu. We should be able to launch that new panel or the joint infection panel in 2022. As mentioned, also we doubled installed base. So that is room to grow for the mid- to long term also leveraging this installed base, which has stabled, growing also the non-RP panel, and again, I'll be going international, meaning outside of the U.S. remains a key priority for us. But we're also very pleased to know that we will be launching a new BIOFIRE platform, which has been started to be submitted, I think, in December to the FDA.

And as you know, also during the past 2 years, we have seen some movements in the field of diagnostic, and of course, the push for molecular solution, but also the push for decentralized testing solution targeting the patient or end point of care. And this new solution will be clear waved, will have its results in less than 20 minutes. So we are very pleased that to be the first one to bring syndromic testing close to the patient with this new solution, which is under FDA filing at this stage. And I guess more to come when we get closer to the launch.

Pipeline. We know you know that we invest in R&D for today, for tomorrow and that we should also be able this year to deliver important new products and new solutions. We are planning to launch a new VIDAS platform at the end of 2022. We're bringing scalability, connectivity and traceability. In addition, on the VIDAS platform, we'll be able to launch 2 parameters important, the first one being a VIDAS TBI, which is a biomarker to detect traumatic brain injury. And also, we increased our range of solutions to detect arboviruses with the launch of VIDAS chikungunya.

Looking at the industrial application also, both food and pharma will have an important launch as in the fast pace. We are launching the Industry 3P range bringing automation, software traceability, integrity of the results also. And this is -- we start working -- implementing distinct solutions with selected customers in 2022. And in the field of food testing and quality control with good performance in 2021, mainly on the molecular [arranging]. And I will keep on, I would say, developing new assays running on our GENE-UP equipment and also targeting a new market initiative for the food applications. So a good pipeline of new solutions, maybe the next one.

Also, we mentioned I think last year, we formalized our CSR ambition, which is really embedded into the bioMérieux strategy around 5 pillars: health, planet, health care ecosystem, employees and extended company. And that we have been able also to, I would say, deliver and agree on some key important KPIs that we will follow and that will deliver on both for 2025 and also for 2030.

With this being said, regarding 2022, we are also planning for, hopefully -- for a station where COVID is becoming endemic. And with this, we should see a decrease regarding the demand for RP panels. So we are selecting sales to be between EUR 3.2 billion and EUR 3.3 billion, reflecting the regular growth -- negative growth between minus 7% and minus 3%. All of these are in a very volatile environment.

Regarding the CEBIT, also we'll be targeting to be in the range between EUR 530 million to EUR 610 million, of course, leading to the decrease foreseen in terms of sales, but also knowing that we'll be able to invest more in the upturn and customers facing activities supporting our key launches, supporting the clinical studies. And also like everyone, we'll be facing inflation on the salary but also on raw material. So all of this will be done by keeping strong investments in R&D and also in CapEx, which should be around 11% of our consolidated sales.

With this being said, I believe, Franck, we can open the floor to questions.

Franck Admant - *bioMérieux S.A. - Director of IR*

Yes.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We'll take our first question from Maja Pataki with Kepler.

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

I have 3 questions, please. First of all, Alexandre, on the new BIOFIRE platform. Can you -- can you tell us something about the panel? Is it going to be the full respiratory plus some sore throat pathogens on it? Or is it like a slimmed down version of the respiratory? And shall we expect that you're going to put the full menu of BIOFIRE over time on the new platform with less than 20 minutes turnaround time? That will be the first question.

The second question with regards to the new VIDAS platform. You talk about scalability. Are you increasing the throughput? Or how shall we think about that?

And then the last question is with regards to inflation. Can you please be a bit more specific how much -- how many millions, euro millions you're seeing as new headwinds in inflation that wasn't -- that you couldn't anticipate late last year? And how much of that would be -- can you pass on? And which part do you think you won't be able to pass on?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Okay. Thank you, Maja. I will start with the new BIOFIRE platform, which is not closed yet. It's only at this stage of file with the FDA. We are waiting for reviewing and there is some backlog. But yes, for us, it's very important. It has been a key investment for us this past year. So it's a way for us to enter into the decentralized testing space, bringing a [single] solution. And yes, to your first question, it will be with addressing a respiratory and sore throat with less than 20 minutes turnaround time.

Today, that's what we announced. I will see we'll see for after, but usually, we don't launch the platform with only one panel. But then again, maybe -- I wouldn't say it's kind of achieving, but let's wait to have the official launch or when we'll be closer to the launch. But since FDA filing is starting, and we felt it was important to share with you.

VIDAS platform. Yes, the scalability will be able to bring a higher throughput to the platform and VIDAS also will be able to transfer most of the VIDAS target existing today and VIDAS on this new platform.

Question on inflation, Guillaume, I'll let you answer.

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

Yes, of course. So inflation, as every company in the world, I think we see an accelerated inflation since especially the last, let's say, 4 months. When I say accelerated, I mean, on the raw material, but I also mean on the salary, on the tensions on some labor markets. That's clearly are stronger than they were 5, 6 months ago. So what we took into account to try to summarize in the -- let's say -- I'm talking about the midpoint of our guidance, is roughly EUR 50 million on the salaries and the salary increase, which would be higher than usual salary increase and about, let's say, roughly EUR 20 million on the raw material. Yes.

And of course, the question you're very right, is the pass-through. So we have taken and we are taking actions for some pass-through. But of course, in our industry, there are some tenders, multiyear contracts, et cetera. So even though we are quite confident on passing through, it's not a direct and immediate pass-through. So there can be some time lag between our actions and the full pass-through of inflation.

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

Maybe just a quick follow-up, Alexandre. On the decentralized placements of the new BIOFIRE platform, should we think about it more like emergency room settings and clinician clinics, like that? So really, take it out of the lab, put it into clinic setting?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Yes, it could be the plan, yes, because it could be a clear waved, so it could be used by non-lab professionals.

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

And sorry for another follow-up on that, but you did have the respiratory clear waved a couple of years ago. I don't know whether it was 4 years ago or something. And it seemed like it never really made big inroads in the U.S. in the nation offsets or am I wrong? Can you talk about that and maybe say what it was...

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Not, but we would say transparency was a way also for us to test the market as you see the adoption around this type of platform. I believe in COVID times, I think we have seen some good success also on this platform. But again, this will have a much shorter turnaround time. So it should be more fitting the needs of decentralized testing.

Operator

(Operator Instructions) There are no further questions at this time.

Franck Admant - *bioMérieux S.A. - Director of IR*

Maybe we can take questions from the chat. And the first one is from Christophe-Raphael Ganet and talking about -- he's asking for how much BIOFIRE revenue comes from non-U.S. sales?

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

So non-U.S. BIOFIRE is 27% in 2021. It was actually 23% in 2020. So we are continuing to increase. And Japan, Japan is -- I think we mentioned, is now the second country, of course, far from the U.S., but overall took all the other countries, Europe, et cetera. So definitely a great success in Japan.

Franck Admant - *bioMérieux S.A. - Director of IR*

And what is your assumption on COVID test prices by 2022 compared to 2021?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

I would say on the syndromic market where we are positioned so far, we might see a slight pressure, but nothing significant so far. So for me, it will be more on the single tax rebate has happened already. So we are -- the plan is not to be too impacted.

Franck Admant - *bioMérieux S.A. - Director of IR*

Questions from Louise Boyer. What is the chunk of your sales related to COVID?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

So that's a difficult one. As you know, of course, our competitors are very much communicating on COVID, non-COVID. The difficulty for us is that you understand that syndromic testing, respiratory panel, is not a single COVID test. It's a test that tells you if you have a COVID, flu A, flu B, RSV and I don't give you the list of the 28 or 27 pathogens in the panel. So it's more -- as it says, it's a respiratory syndromic panel. So we cannot really classify it as a COVID-related sales even though, of course, COVID and COVID demand and the most severe cases of COVID, whilst fueling the demand for this panel that's something...

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

But what is sure, we know that we hope that we're moving into the endemic phase for sure, the COVID-19 market will decrease. I would say, practically, this year, hopefully. But we believe that syndromic is the right technology to address an endemic market knowing that COVID-19 will be part of -- for many years will be part of the different assays that we have to test. So we [have market share].

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

And so that being said, again, we don't classify the respiratory panel as COVID because, again, it's broader. But yet, if you want to think about it, respiratory was 72% of our BIOFIRE reagent sales in 2021. And on top of that, please remember that we had also and I have mentioned it, some COVID-related additional demand on immunoassay in 2021 that is COVID becomes endemic will slow down, of course.

Franck Admant - *bioMérieux S.A. - Director of IR*

The second question from Louise is about the future growth drivers for sales and margin.

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

So the growth drivers we mentioned in terms of trends you might have seen in the outlook. So if we take it by segment or technology, microbiology is a market where we have very strong positions. The market itself is probably a 4%, 5% market growth, and we expect mid-single-digit growth, probably slightly higher than the market. That's what we've been able to do in the last 2 years.

On immunoassays, we have, as you've seen some positives and negatives, negatives being especially the PCT pressure, positives also are emerging positions, emerging market positions. So overall, a stable to slightly above stable outlook. We expect a very strong growth from nonrespiratory panels as we have shown and been able to deliver last year and the past year, actually. And industry expect a mid- to high single-digit growth that was, again, on strong fundamentals on top of our own, let's say, actions and portfolio, as Alexandre detailed.

Franck Admant - *bioMérieux S.A. - Director of IR*

The next one is coming -- yes. The next one is are you working as a COVID name? What are you now, what is your [pretty] story?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

So I will take this one calmly. No, we are not a COVID company. We have been present for close to 60 years. We are a company focusing on infectious disease through the value of diagnostics, investing in R&D, net capacity and manufacturing. We existed way before COVID and we have a long story after COVID, even if COVID will stay for some time. And our story is about bringing innovation time to market, time to results for industry, that infectious disease.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question still from Louise about expectation on BIOFIRE development outside of the U.S. and a number of units that we are expecting to improve.

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

So we expect to continue to grow and to grow strongly outside of the U.S., as we've shown in the past year. Actually, the growth in the U.S. has been good but was even higher outside of the U.S. We mentioned Japan, but we can mention Europe as well in '21. That performed very well on syndromic testing. I mentioned Latin America as well. So we expect to pursue the growth of BIOFIRE outside of the U.S.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question from Christophe...

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

And maybe also -- the question from the [line]

Franck Admant - *bioMérieux S.A. - Director of IR*

Is there somebody from the call?

Operator

Yes. We have Ms. Pataki again, queued. You want to take the question? Ms. Pataki with Kepler.

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

So I'll keep asking if no one else wants to do. Just a quick question. Can you quantify the Field Corrective Action? How much was it in Q4? And how much of that was in China? And then thanks for the elaboration that virus is going to be a higher throughput. But can you maybe compare it a bit to your competitors? Are you going to be closer to [Deliazoic's S] platform, and therefore, the latent TB competition starts to level out a bit?

And then the third question would be -- I mean, I do understand that it's difficult to pass on this amount of inflationary headwinds. But in which areas do you believe can you easiest increase prices? Would that be BIOFIRE? Or would that be in your other -- in your other businesses?

And then for now lastly, do you believe that M&A is now more a topic for you to broaden your offering? Or do you think you're well established to deliver attractive growth going forward?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

I will start with the M&A question. I will leave Guillaume with the easy questions. No. I mean no, we remain active in M&A. We are also lucky, lucky enough, but now we are a debt-free company. So we have room of maneuver, and we remain active to look at technologies or companies which are -- which can bring -- which can complement our portfolio or what we like in bioMérieux also new emerging technologies which have the potential to improve patient care and also this is into -- time to results. So we are -- we're still going.

At the same time, I believe I showed the pipeline. We have a healthy pipeline coming from our years of investment in R&D. But we'll stay open and pragmatic. So Guillaume?

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

So your question was about the Field Corrective Action. So the viral Field Corrective Action in Q4. So the overall P&L impact is EUR 20 million in terms of EBIT in Q4. So it's a mix of some of the credit notes that we had to make some use to some customers, some scrap and also some replacement of VIDAS products via new ones. It's more difficult to assess on the sales part because some not ordering is difficult to exactly catch. But I would say, ballpark, it's about EUR 20 million as well on the sale. And I just reiterate that it's fully sold. I think we managed it well. It was a difficult topic high hitting all of the assays from this quality issue of the supplier.

But we manage it well and quickly to replace, it's now fully resolved. And you had a question about the price increases. I would say that it -- it depends on our position in every country and every, let's say, product segment, which are very different actually from one country to another. So I wouldn't say there's one major rule of thumb that we can give. So our general managers are looking and pushing and acting, let's say, country to country and segment by segment.

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

And the VIDAS throughput?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Yes. Focus will be higher, thanks to scalability. I should know but to be frank, I didn't compare to [Deliazoic's S] to this recent launch. We did it because we felt that there was a need or a demand for in throughput. And by the way, both for clinical and industrial applications, but we followed our path there. I didn't compare to excess.

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

Okay. And maybe just one more that came up. I mean, you have doubled your installed base in BIOFIRE. But do you have any visibility or data that you could share with us how many of the 10,000-plus have gone to new customers and how many have gone to repeat customers?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Guillaume?

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

So on the year, we -- on the U.S. additional installed base, that's why we can really follow. We have about 64% that was additional capacity with existing customers and 36% that were with new customers overall on the increase, and we gained approximately 200 new customers in the U.S. These were U.S.

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

So the 36% new customers is U.S. as well?

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

Yes.

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

Okay. And then international is obviously mostly new customers?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Yes, mostly, yes. We don't have the precise measure, but yes, of course, mostly.

Franck Admant - *bioMérieux S.A. - Director of IR*

So let's move to a question from the chat. Question from [Mark Batione]. What you forgotten for? Yes. Will you use some excess cash flow for buyback?

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

So we don't have -- we do stock buybacks, but only to cover our, let's say, free share programs. The usual free share programs, but we don't do. It's not part of the company policy to do stock buybacks just for [dilution] of the shareholders. So only to cover management and employees and talent free share programs.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question from Christophe Ganet, how much of the OpEx were reduced due to the pandemic compared by 2021?

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

So thank you for the question. I think we have communicated a number of times that it was a very significant reduction. So several tens of millions on the different lines, overall. We always mentioned travel, Congress, marketing, but it's also impacting other lines. For example, clinical trials, which is actually costing the R&D line, were postponed due to COVID with difficulties to recruit patients for some clinical trials. And that's also significant savings. And so there are savings in a number of lines. What we have factored in our 2022 guidance is actually with COVID becoming endemic, a progressive come back and ramp up of this cost in the view that we want to invest as Alexandre said, for the future of bioMérieux, be it in R&D and clinical trials.

I just mentioned, be it also in the commercial activities, more customer-facing, pushing our all new products and new launches with our customers.

So that's all factored in this higher cost, very visible higher cost base in '22 guidance.

Franck Admant - *bioMérieux S.A. - Director of IR*

Next one is from Christophe. What level of CapEx should we expect from '22 and '23?

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

So we -- '22, we gave it. So it's 11% of sales -- or around 11% of sales, it's not exact. And beyond that, I would say the 10% is a good overall benchmark over time.

Franck Admant - *bioMérieux S.A. - Director of IR*

And last one from Christophe. Do you have an issue on supply chain, any issue on supply chain?

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

So supply chain, we have issues for the last 2 years with all the difficulties that you read everywhere, with ports being blocked, high -- much higher cost of transportation. Of course, the bigger topic today is about the Russia, Ukraine topic, but that's a very small part of our revenues. We can say it is tense, but managed, the overall situation. Yes.

Franck Admant - *bioMérieux S.A. - Director of IR*

And the next question is about Russia from [Thibaux] . So what is the percentage of sales volume of Russia?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Russia [percentage] I can say this is less than 1% of the revenue of bioMérieux, but we have a strong team over there. And we are not present in Ukraine directly. We have a distributor.

Franck Admant - *bioMérieux S.A. - Director of IR*

And another question from [Thibeaux]. Can you be more specific on your sales guidance, how to justify the low and high range?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

I think I won't surprise you saying it's a very volatile environment at this stage. It was not so even easy, I would say, to give a range for this year. It will depend a lot of -- hopefully moving into endemic, but we'll see what happens. I hope there won't be more variants. We'll see if we'll finally have a flu season next year, which was not the case this year. So it's a little bit of a time environment. So this is, I would say, the projections that we are making at this stage with the visibility that we have. It's not so easy, I believe, for us and for the diagnostic industry to predict what will happen. But I would say, in our view, this is into the endemicity of COVID.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question from Lauren (inaudible) [Charlotte] Investors. Any reflections from the Field Corrective Action? Any key learnings?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Any new learnings, but that's part, I would say, of what we do in our industry. Sometimes we rely on some key components or small components or substrates that we have to deal with. Key learning, I would say, first, maybe internally, it was well managed internally. This crisis because it was a crisis, but the idea was not to impact too much the customers or mainly the patients. But I would say that's part of our life. But it means we have a strong scrutiny on the different suppliers at different levels, but also a strong scrutiny on the quality of the raw materials that we use. But no specific learnings. Maybe, Guillaume?

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

Yes. Just to add, we -- on top of what Alexandre said, we also had a good management internally, but also in a good partnership with the supplier, really good work together. And beyond that, we have a number of raw materials that are on the single-source mode. And actually, we have launched, but not from this Field Corrective Action. That's a decision we took more than 1 year or 1.5 year ago, a 3-year plan to really manage the most critical single source topics that we can have in our portfolio and to find risk mitigation actions that can be sometimes double sourcing.

Franck Admant - *bioMérieux S.A. - Director of IR*

Next one from [Juan] [Why go forward] with earnings guidance?

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

Why do we make even an earnings guidance? Again, as Alexandre said, it's a very volatile environment. And it's true that I think one of our competitors did not make any guidance. We thought -- we thought about it, but we saw that the best, let's say, approach, even though things are moving so

fast that the best was to give you our best view as of today. And again, it's a very difficult exercise for us, but we share with you what we see today. Maybe we shouldn't have.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question from (inaudible). The top line guidance looks quite conservative. To get there, we almost need to assume that molecular [microbiology] comes back to 20%. I'm getting 20% of overall sales and overlying 30% [with income]. Are these 2 divisions that benefited from COVID, what about immunoassays?

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

So -- maybe if I can comment yes, of course, we assume BIOFIRE syndromic respiratory to go down. I think it's not a surprise to -- it shouldn't be a surprise to anyone that it was boosted by COVID in the last 2 years, even though, again, it's syndromic. It's a product and a diagnostic product that goes beyond COVID for other viruses that will be used for respiratory pathogens beyond. But yes, so in 2022, we do factor or slow down about 25%, 30% of decrease of demand but linked to COVID a decrease of demand on [respiratory COVID].

Franck Admant - *bioMérieux S.A. - Director of IR*

Question from [Thibeaux] regarding M&A. Are you looking at new technologies? And would you willing to use leverage like in the past at the BIOFIRE acquisition?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Yes, we are. Sorry. We are -- again, we are pragmatic. We're also entrepreneurial. We know when to take bets. So yes, we will use the tools which are keeping bioMérieux, of course, secured, but we look at different options here.

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

Immunoassay, the other question about immunoassay guidance and more details about the headwinds. So just to reexplain situation in immunoassays. So you know VIDAS is a low mid-throughput platform. So we are not fighting on the high year throughput part. On the negatives, we have first the lab consolidation that is going on in Europe and in other parts of the world. But, of course, when labs consolidate, they go to broader or bigger, let's say, common platforms with higher throughput. And therefore, we -- by that tends to be displaced because it's a low throughput platform. That's the first negative.

The second big negative is procalcitonin in U.S. and China. We were, let's say, kind of alone in the U.S. until 2017. Competition entered progressively. So we have a volume and price pressure over time on this parameter.

On the positives, we have first our innovation as Alexandre explained, we launched and will continue to launch new assays to complement our portfolio and increase our sales. One of the good examples recently was the latent TB with TB-IGRA launched in '21.

And the second positive is that VIDAS has a strong position in emerging countries for large -- where the broad menu on immunoassay and the low throughput is adapted. And of course, that's a growing position. So between this, let's say, 2 negatives and 2 positives, we expect some, let's say, stability in '22 and maybe a bit better than stability beyond that.

Franck Admant - *bioMérieux S.A. - Director of IR*

Okay. So both the commercial ramp-up of activities, to support future growth, are you able to quantify the incremental spend?

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

I can mention one element, which is because we talk so much about travel, marketing, Congress, inside of the sales and marketing. If you take the midpoint of our guidance, it's, let's say, roughly to give an idea, about EUR 30 million of additional spend on this kind of nature of costs that we expect. And again, we believe these are important spend to fuel our growth for the future and to push our new products.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question, can you comment on M&A? Yes, question. Can you comment on M&A? Where do you see the future of diagnostics? What about Caregen?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

How I see the future of diagnostics, I would say, bright, I would say, closer to the patient. And I would say also with a stronger impact on patient care. And I believe this is what COVID has demonstrated, I would say the value of diagnostics, and view also our job, us and the other players such as Caregen about [the debt waiver], that will be our job to promote and defend the value of diagnostics, but no specific comment on Caregen to make.

Franck Admant - *bioMérieux S.A. - Director of IR*

Question from Hugo Solvet, PCT testing. When could we expect price pressure to stabilize or annualize?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

PCT I think there is still a trend to -- at least in the U.S. on price pressure, but when we stabilize, I don't know. If you could -- but there is less and less pressure, I would say now that we have more competitors. So we'll start -- we continue to see pressure, but I would say less impacting than it was the last 2 years.

Franck Admant - *bioMérieux S.A. - Director of IR*

Next question from (inaudible). [Can you divulge the] split of BIOFIRE share between U.S., Japan in Europe.

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

So we gave U.S., non-U.S., which is 73% U.S. and 27% non-U.S. We have not split the non-U.S. between Europe, Japan and LatAm.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

But I believe we said that Japan has become #2 market for us. By the way, also linked to the COVID-19 crisis that end of last year, I believe it was #2 country for us.

Franck Admant - *bioMérieux S.A. - Director of IR*

Any update on VBP from China?

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

So we have not heard a -- so VBP is the volume-based procurement. Some of you know that this was a new way to buy in China that was tested in one province, Anhui province in China that went through with pretty major price decreases, around 50%. It's a very small province. [IBO] the local immunoassay company participated. We don't see any, let's say, extension or actually roll out of this kind of policy through any other province yet. Immunoassay might be compared to pharma, a very small market and complex to organize for this.

Franck Admant - *bioMérieux S.A. - Director of IR*

Coming back to price pressure, but this time on [syndromic testing]. Are you seeing any more on RP or non-RP finance, continuing price pressure?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

To be frank, not so much in the recent context. We cannot say there was intensified pressure, both commercially, I would say, on price.

Franck Admant - *bioMérieux S.A. - Director of IR*

Any update on specific deployments?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Also, we started the co-distribution in September, I guess. So we are still in a phase where we are, I would say, promoting and doing some pilots on this evaluation of technology, which looks quite interesting seen from a customer perspective.

Franck Admant - *bioMérieux S.A. - Director of IR*

Coming back to Russia. So the size of the [limits] we already answered with less 1%. But how do you think the current crisis will impact the business?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Difficult to predict. It will depend on the embargo conditions, but we are there to serve public health. So we will attempt, I would say. But then again, very difficult to have a visibility on this very tough situation.

Franck Admant - *bioMérieux S.A. - Director of IR*

Are there questions on the line?

Operator

Yes, we have one more question from Maja Pataki with Kepler again.

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

Just a quick follow-up on that. I couldn't really understand. The VITEK MS PRIME, when are you expecting the U.S. launch? Is it 2022 or 2023?

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Sorry, Maja, we had a short disconnection. So can you repeat your question?

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

Yes. Sure. The VITEK MS Prime launch in the U.S. Is it '22 or '23? I couldn't crystal clear understand it.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

We expect to be in '22. But to be frank, there is some -- FDA is quite busy. So this could cause some backlog linked to COVID. But our expectation is for '22, but it's difficult to talk for them.

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

Of course. But let's start with the expectation and we see what comes out...

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

The expectation is for '22.

Franck Admant - *bioMérieux S.A. - Director of IR*

So maybe a last question from the chat.

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

I had another question on (inaudible) and the rumor of we had last year. So we -- again, we have said already that we don't comment on rumor, always the same, let's say, rumors on the big usual suspects in the industry as there are not many companies of 5 and mid-caps, (inaudible). So no specific comment.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

No more questions from the chat. Is there any questions from the call?

Operator

There are no further questions on the phone.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

So I think we can end up the call right now if there is no more question. Okay. Thank you very much. Thank you very much participation and attention. I'll just remind you that the next release will be on April 27 concerning our Q1 sales performance. Thank you very much indeed for your attention. Bye-bye.

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

Bye-bye.

Alexandre Merieux - *bioMérieux S.A. - Chairman & CEO*

Thank you.

Operator

This concludes today's call. Thank you for your participation. You may now disconnect.

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