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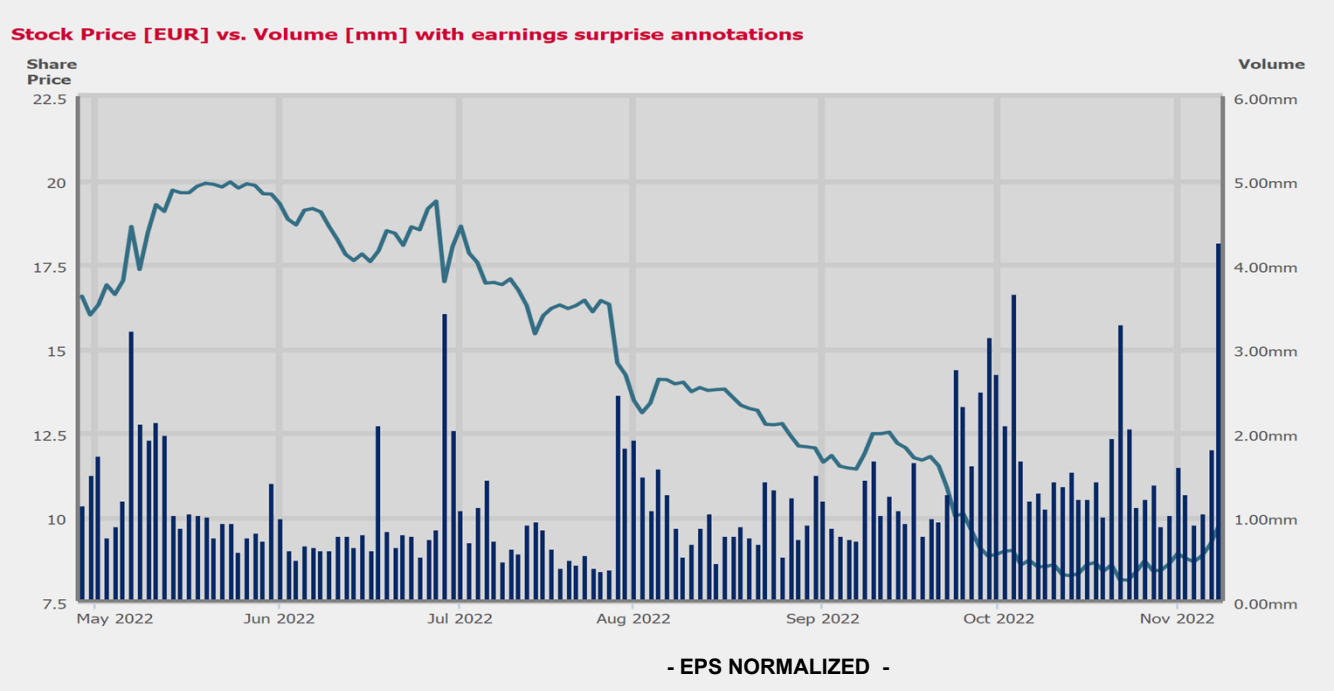
FQ3 2022 Earnings Call Transcripts

Tuesday, November 8, 2022 1:30 PM GMT

S&P Global Market Intelligence Estimates

	-FQ2 2022-			-FQ3 2022-	-FY 2022-	-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	NA	NA	NA	NA	0.65	NA
Revenue (mm)	1567.75	NA	NA	1598.96	5834.97	NA

Currency: EUR
Consensus as of Nov-08-2022 7:40 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ3 2021	NA	NA	NA
FQ4 2021	NA	NA	NA
FQ1 2022	NA	NA	NA
FQ2 2022	NA	NA	NA

Table of Contents

Call Participants	.....	3
Presentation	.....	4
Question and Answer	.....	11

Call Participants

EXECUTIVES

Alfredo Arroyo Guerra
CFO & VP

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Steven Francis Mayer
Executive Chairman

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

ANALYSTS

Alvaro Lenze Julia
Alantra Equities Sociedad de Valores, S.A., Research Division

Emily Field
Barclays Bank PLC, Research Division

Guilherme Macedo Sampaio
Banco BPI, S.A., Research Division

James Daniel Gordon
JPMorgan Chase & Co, Research Division

Julien Dormois
BNP Paribas Exane, Research Division

Rosie Turner
Jefferies LLC, Research Division

Sarita Kapila
Morgan Stanley, Research Division

Thomas M. Jones
Joh. Berenberg, Gossler & Co. KG, Research Division

Vineet R Agrawal
Citigroup Inc., Research Division

Presentation

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Good day, everyone, and welcome to Grifols Business Update conference call. We are very pleased to host this call today, and thank you for joining.

As we have already explained, we want to increase our engagement with the capital markets and with investors. This is a testament to our commitment to enhance our communication. The call will last 1 hour. There will be a presentation of something like 30 minutes, and then we will follow with the Q&A session of -- to complete the hour, or if you have no questions, we'll finish earlier.

Today, I'm joined by Steve Mayer, our newly-appointed Executive Chairman; Raimon Grifols; and Victor Grifols Deu, our co-CEOs; and Alfredo Arroyo, our CFO. The materials of this call are already available on the Investor Relations section of grifols.com.

And then, well, our forward-looking statement disclaimer here for this business update. We undertake no obligation to update or revise any of these statements. And this is -- the forward-looking statement refers to the substantial risk and uncertainties.

And with that, I will turn the call over to Steve. Thank you.

Steven Francis Mayer
Executive Chairman

Thank you, Nuria, and thank you for everyone for joining the call today. Since I am new to the Grifols Executive Chairman role, I would like to begin the call by emphasizing a few high-level points before we turn to the specifics of our business update.

Many of my friends and acquaintances have asked me why I elected to take on this role at Grifols at this point in my life. The answer is actually pretty simple. Grifols is a great company with a clear mission and a long history of improving the health and well-being of people around the world. It also has very strong fundamentals in place, irreplaceable assets supporting a long-term strategy, and the challenges it has recently faced can, and will be overcome.

I've recently read a few reports that have questioned whether in light of the fact that I've been on the Grifols Board for several years, there will be any real changes in the offing. In response to that question, on the one hand, I can refer you to my long private equity career that was focused on being a change agent and helping companies that we own to realize their potential.

On the other hand, I also fully recognize that words are not what matter, our execution and our performance will ultimately tell the true story. I ask that you judge us on our strategic, operational and financial performance over the coming months, which is how we will be judging ourselves.

If you check out my personal background, you will also know that I'm highly competitive and driven to win with a lot of experience in team sports. While I am now ultimately responsible for delivering, at the same time, you should know that this is one team, and we will align as a single unified team behind our goals. In that regard, we are, as a team, laser-focused on our top priorities.

First of all, creating an organization with a performance culture that will be efficient, effective, data-driven, agile and decisive. We are already implementing a renewed emphasis on planning and execution. Again, if you look at the investments I led at Cerberus, you will see that in most of them, improved operational performance was at the heart of their success. That improved performance comes from a disciplined approach to planning, project management and rigorous execution against the plan.

I also believe strongly in the principle of accountability. Everyone in the organization will be accountable using measurable indicators, starting with me. We will also be much leaner and more cost effective and while this will improve our margins, just as importantly, it will enable us to move faster and serve patients better.

Our next priority is to meaningfully improve our cash flow and expense profile. We have been making and expect to continue to make progress on the cost of plasma. Of course, there is a 6 to 9-month lag before cost reductions are recognized in our income statement as a result of our long inventory cycle which, as you know, is characteristic of our industry. We are also focused on reducing fixed and semi-fixed cost throughout the organization from delayering, better spans of control, organizational streamlining, facilities rationalization and capacity optimization, outsourcing, sourcing certain non-core functions and better use of technology and data. We're also making further effort to reduce working capital and CapEx cash use. And very importantly, we are implementing a zero-based budget process for 2023.

A third and very important priority is debt reduction. Right now we are evaluating a variety of levers and although we have nothing to announce today, it is clear that the company has highly valuable assets throughout the world, and therefore, we have a range of attractive deleveraging alternatives under consideration. We do, however, believe that the company's stock is meaningfully undervalued today, so issuance of equity in today's trading range is not a favorite option. We firmly believe that by year-end 2023 and very possibly before, concerns about leverage will be substantially mitigated.

Our fourth priority is capturing commercial opportunities with certain of our existing products that we believe are underpenetrated currently. For example, our subcutaneous IG product, which commands a higher price than IVIG, represents only a single-digit percentage of our IG sales compared to 40% for CSL. In addition, we continue to see opportunities for our high-margin alpha-1 product, PROLASTIN, through ongoing efforts in patient identification. We will be mentioning a recent favorable development in that regard later in this call.

Our final top priority to mention today is in the effort to unlock the full value of Biotest. We in Biotest are dedicating resources to accelerate integration and the recognition of both cost and revenue synergies. As you know, we also believe that the approval, commercialization and successful launch of the new Biotest proteins are likely to have a substantial impact for Grifols's financial profile. Of course, any initiative that's dependent on regulatory approval and successful commercialization and market launch inherently involves uncertainty, but we continue to believe that fibrinogen and IgM are a matter of when, not if, and that ultimately, it will be very significant and high-margin contributors to profitability.

In addition to these 5 key priorities, we plan to continue improving transparency and enhancing our communications with the capital markets and with investors. Today's call is evidence of this. We also expect to schedule the meetings with individual investors once we have progress to report the priorities I've just walked through. I look forward to meeting many of you in-person before too long.

Before turning the call over to Raimon and Victor, I do want to state that it is highly important to me to ensure that we deliver on all of our goals while remaining true to Grifols' core values and sustainability.

Raimon and Victor?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Thank you, Steve. Thank you all for being in the call here today with us.

I would like to start by highlighting the 2 recent leadership appointments that communicated the recently announced reorganization. We have appointed Pia D'Urbano to lead our Biopharma business unit and Jordi [indiscernible] to lead our Plasma Procurement business unit.

Pia brings with her 29 years of experience in health care, particularly in biotherapeuticals, including her conservative roles in top management, multinational companies like Sanofi or Novo Nordisk in the U.S. Her experience spans global product launches, new product planning, establishing new businesses, heading marketing and sales, business development activities, a strategic planning and alliances development. She's an impressive executive, and her broad experience with market launches of new products is expected to be especially helpful as we look forward to launching the Biotest in proteins for example.

We have also named [indiscernible] for the Plasma Procurement business unit. [Jordi] held various roles during his professional life, with a special focus on the retail distribution channels worldwide and global expansions. His experience also includes building local teams and subsidiaries, developing relationship with the strategic partners, deploying omnichannel and high-tech projects. All this knowledge and experience in retail business will for sure reshape and evolve the way Grifols has historically approached the management of Plasma Procurement operations. I'm sure that this will move us to a more efficient and bigger sourcing network. We are all looking forward to working with them.

Now, changing gears to the Q3 '22 highlights and the financial performance.

Let me start with revenues. And really, I am proud to say that Grifols delivered very strong operational performance in the third quarter, leading to a solid Q3 year-to-date 2022 number while operating all that in a very complex macroeconomic environment. Compared to Q3 '21, global revenues on a combined basis were up 23% operationally, reaching EUR 1.5 billion revenues. On a reported basis, this growth represented a 37% increase due to the foreign exchange sale rate. Underlying a stand-alone operational performance has been the driver, with revenues growing at 13.7%. Of these underlying drivers for the quarter, expects to higher plasma collections in the first half of this year 2022, driving volumes of key proteins, especially hemoglobins, together with pricing upticks, product mix and the Biotest contribution.

Year-to-date revenues totaled EUR 4.351 billion, increasing by 9.5% on constant currency and 18.8% on a reported basis compared to the same period 2021, with a stand-alone operational performance of plus 3.8%. Regarding plasma procurement, following the latest updates, plasma collection volume grew by 25% in the first 42 weeks of 2022 versus the same period of 2021, which we anticipate will underpin a strong sales growth in the second half of the year and onwards. We need to continue to build on this momentum in the coming future.

Additionally, the lifting of the restrictions for the Mexican donors in mid-September has also started to contribute notably to future increase in plasma donations, and we expect it to continue to do so.

In terms of EBITDA, volumes, pricing, operational leverage and cost discipline partially offset cost per liter and inflationary pressures to drive reported EBITDA to EUR 927 million, representing a 21.3% margin on sales. Excluding Biotest, it stood at 22.2% of sales. Adjusted EBITDA was EUR 899 million with an adjusted EBITDA margin of 21%. And excluding Biotest, it stood at 20.7%.

Paramount in the industry is the balance between volume of plasma and its cost. As plasma collection volumes normalize, we are now focused on driving cost per liter reduction by driving lower donor compensation, optimization of labor costs and the rest of the fixed cost that are impacted in the cost per liter.

Donor fee is one of the key components of the cost per liter, accounting roughly to 35% of the fully loaded cost, and therefore, the one that has made an impact in the short term. Since its peak in July this year, donor fee declined at more than 15%. Comparing September versus January, it declined at a total of 7%. And at the same time, since volumes are sequentially increasing, the fixed cost portion of the cost per liter benefits from operating leverage.

We firmly believe that this time will be sustained, and we are confident on our future -- on a further reduction from now to year-end that will positively contribute to profitability going forward. We will continue assessing the write-off between plasma collection and donor fee and balancing these 2 components to enhance our performance. Moreover, as restrictions for Mexican donors were lift, there is a significant upside to further increase plasma collection, which will certainly determine our decisions on donor fee evolution.

Regarding deleveraging, the reported leverage ratio declined from 9.0x in the first half of 2022 to 8.6x in this last month, September 2022. And it is expected to stand below 8x by the year-end, specifically at 7.9x. As we are focused on driving donor fee reduction, cost optimizations and operational efficiencies, this is expected to trigger more EBITDA and working capital improvements throughout 2023, leading to a further evolution on the leverage ratio.

After 2 years of highly complex pandemic environment, the test severely impacted the plasma industry and are now followed by its consequences in the midst of this changes in macroeconomic backdrop will lead it from 3 different -- we see it from 3 different angles. On the one side, inflation and the current challenging macroeconomic context are further driving plasma collection momentum, which can potentially contribute to further cost per liter reduction.

On the other side, macroeconomic backdrop is impacting our labor cost to some extent, especially those in our plasma centers. And third, our exposure to interest rates hike in [indiscernible], as close to 65% of our total debt is tied to a fixed interest rate.

And to finalize these highlighted sections, I will move to the innovation pipeline. Certainly, we continue to advance on our most advanced programs of our innovation pipeline such as fibrinogen, IgM, albumin cirrhosis and anti-inflammatory subjects among others. But in this quarter, please let us highlight that we received FDA clearance for our AlphaID At Home product, the first free service for U.S. users to screen for the genetic risk of alpha-1 antitrypsin deficiency that doesn't need subscription -- prescription service from the medical professionals.

And now, let me please transition to Alfredo, who will give us further details on the financial performance.

Alfredo Arroyo Guerra
CFO & VP

Thanks, Victor. Hello to everybody, thanks for joining this call. Now let's review our P&L.

Starting with revenues. Grifols delivered very strong operational performance during the third quarter. Compared to the third quarter of 2021 global revenues were up by 23% at constant currency, reaching EUR 1.5 billion, and a 37% growth on reported basis. Robust revenue growth was driven made by Biopharma's key proteins following increase of plasma supply, positive product mix, positive pricing and very positive FX tailwind, as well as significant contribution from Biotest at 5 months, circa EUR 200 million.

Gross margin was impacted by a high cost per liter from the plasma collected in the first half of the year due to mainly high dollar compensation and labor costs impacted by inflationary pressures. Additionally, it is not worthy to mention the negative impact for the

high-margin diagnostics business, triggered by the end of the one-off COVID testing, and mandatory Zika screening, which largely impacted gross margin by 180 basis points versus Q3 '21 and 250 basis points versus Q3 year-to-date September '21.

At the EBITDA level, we were able to offset the impact at gross margin level and delivered a sequential EBITDA global expansion, which was supported by operational leverage, cost savings and R&D prioritization. Inflationary pressures were partially offset at OpEx level as well. And net income totals EUR 188 million profit, which reflects higher financial expenses linked with Biotest acquisition bond and higher interest rates.

Now moving to Slide 9, revenue performance. Our main division, Biopharma, revenues reached EUR 1.3 billion, EUR 1.2 billion excluding Biotest during the third quarter of 2022, growing by 34% at constant currency and close to 50% on reported basis. Thanks to positive FX income. As mentioned, several drivers were behind this strong performance including robust immunoglobulins, underlying demand, the larger plasma supply, prices increase and product mix. Specially significant were the sales of our subcutaneous immunoglobulin. Thanks to higher demand and a favorable customer mix.

Year-to-date, Biopharma sales stood at close to EUR 3.6 million or EUR 3.4 billion, excluding Biotest. This represents a year-over-year increase of 16% at constant currency, 26% on reported basis. Excluding Biotest, Biopharma revenue grew by 8.7% at constant currency and 19% on reported basis in the first 9 months of 2022 compared to the same period of 2021. The sales performance reflects sequential accelerated growth of 21% at constant currency in the third quarter compared to 0.1% growth at constant currency in the second quarter and 7.1% growth at constant currency in the first quarter.

The Diagnostic revenues declined by 20.8% at constant currency to EUR 170 million in Q3 2022, primarily due to the non-recurring sales of our COVID test and the termination of the mandatory Zika virus testing, which was partially offset by gross sales of blood typing solutions.

Diagnostic record circa EUR 500 million of revenues during the first 9 months of 2022, down by 21% at constant currency, compared to same period of previous year. Excluding the one-off COVID test and the Zika virus screening, the decline was just 3.5%, mainly due to country mix and price.

Bio Supplies reported significant revenue growth in the third quarter, expanding close to 30% at constant currency, reaching EUR 44 million following the acquisition of Access Biologicals. The business unit grew by 5.5% constant currency during the first 9 months of 2022.

Moving to the next slide, to the margins. Gross margin stood at 38.2%, representing a slight sequential decline from 38.9% reported in the first half of 2022. This reflects a high cost per liter incurred in the first half of the year as a consequence of total compensation and labor cost inflation. Grifols continue to expand and enhance its operations despite inflationary pressure. The company's effort to optimize cost and operational efficiency resulted in a stable cost per liter during the first half of the year despite the 8% to 10% annual inflation in our regions of operations.

On the back of solid plasma collection level, Grifols is focused on balancing volume and cost per liter to drive margin expansion, with an emphasis on reducing dollar compensation and also optimization of labor and fixed cost.

The donor fee, as mentioned, that accounts probably 35% of the fully loaded cost, it fell by 7% from January to September and by more than 15% from its peak in July 2022. Additionally, as mentioned, it's important to highlight the impact of the Diagnostic into gross margin due to the COVID, and once again, the Zika. Excluding that impacted by 250 basis points, the first 9 months of 2022 compared versus previous year.

EBITDA grew up to EUR 927 million during the first 9 months of the year, with 22.2% margin and 21.3%, including Biotech. This represents an EBITDA growth versus previous year of 12.8%.

As I already mentioned, Grifols continues to apply cost discipline through its savings plan and the prioritization of R&D projects, which partially offset the inflationary pressure as well as higher Biotest expenses, particularly related to the Biotest Next Level Project. This accounts for the 5 months period where -- since the time that we acquired Biotest of EUR 35 million.

Adjusted EBITDA for the third quarter of the year has proved to be in line with -- of the first half of the year, reaching close to EUR 900 million with an adjusted EBITDA margin of 20.7%. Here, the adjustment basically are related to one-off restructuring costs as well as one-off external gains. Excluding Biotest, it stood at similar levels of the standalone company.

Moving to the EBITDA sequential improvement. As shown in the slide, in the second half of 2021, the EBITDA was low, especially in the last quarter of 2021, basically since -- due to low sales because lower plasma product as well as certain restructuring and write-

offs that took place in the last quarter of last year. Since then, we have been addressing both the main impact from COVID, which were lower plasma collections, and the higher cost per liter of plasma.

As mentioned, also the impact from Diagnostic division has been significant. We were able to improve EBITDA throughout the 2022 through cost control, R&D prioritization, bringing the contribution of EUR 70 million savings in terms of OpEx.

Also, the positive contribution from Access following the integration, that includes a one-off capital gain. This reach also reflects what I've been mentioning so far, mirroring the sequential improvement.

In the next slide, as already explained, plasma collections increased by 25% year-to-date versus previous year, and to a larger extent, in the U.S., expanding by 28%. Now that plasma volumes increase are normalized, we are focusing on cost per liter reduction, driving dollar compensation [decrease] as well as optimization of labor and fixed cost. There is an ambitious plan to keep reducing cost per liter with the aim to revise this cost per liter. Donor compensation reduction will continue going forward. In addition, optimization of labor and fixed costs, including some plasma centers relocation, consolidation and also closing those less efficient. This will support further reduction in terms of cost per liter.

Having said that, we will continue assessing the trade-off between plasma collections and donor fee, and balancing these 2 components to enhance our performance going forward.

On the leverage, yes, we are laser focused on leverage, and basically, the main levers of the organic deleverage are in this order. First, EBITDA improvement, working on margin, plasma costs as well as OpEx origination. Optimizing working capital. This year, we have to build up inventories. Once last year, the inventories were exhausted as a result of the lower plasma collections. But for the next year, the inventory increase will be limited in line with, I would say, normal times. Also, limited CapEx. No meaningful acquisition, discipline in capital allocation. And since we are well invested, this business require no significant capital moving forward.

This is, as mentioned by Steve, this is in the opening remarks, is a top priority. In Q3, we were able to reduce the 9x as of June, that was the peak of the year, down to 8.6x. By the year-end, expected to further decline and will be around 7.9x. We will continue to evaluate also, as already mentioned, our global wide base of valuable assets for optimization. Important to mention that Grifols' strong liquidity position at the end of the quarter totaled EUR 1.6 billion, including a cash position of circa EUR 500 million, while there are no significant maturities until 2025.

Victor?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Thank you, Alfredo.

Now, we would like to get into more detail about the performance of the business units.

Biopharma, we are optimistic that we are seeing improved momentum evidenced by a strong third quarter across key proteins, especially Ig, our flagship, which grew by 12% in Q3 year-to-date 2022. As global plasma supply decreases, we are anticipating a strong growth with opportunities on core indications, such that primary -- such immunodeficiencies and [NCID].

Demand has and it is expected to remain robust. Many patients even in cloud markets remain underdiagnosed. Furthermore, even though incidences of the diseases are similar across the order phase, consumption rates can vary significantly from one geography to another. Actually, I see in the U.S., for instance, it's still consumed at almost 3x the rate per head of population when compared to Europe.

Noteworthy to mention, our new products continue increasing its contribution. Driven by our core plan to boost our subcutaneous franchise, [indiscernible], to contribute to the revenues performance going forward.

In Albumin, excluding the already-mentioned phasing in the second quarter of the year, sales were flat versus the first 9 months of 2021, with lower volumes in China partially offset by low single-digit price increases. Looking forward, we anticipate volume demand in China to continue to grow at mid to high single digits.

Alpha-1 and specialty proteins delivered a high single-digit growth. Alpha-1 recorded mid-single-digit increase due to a favorable store mix and competitor supply shortages. Additionally, we delivered robust growth of our latest launches, such anti-Rabies, new formulation, tablets and fibrin sealant due to a sustained higher demand, while other more regular products are performing well. All in all, offsetting the FVIII tender pressures that we are seeing.

Moving to Diagnostic. Diagnostic performance has been impacted due to non-recurring sales of the NAT technology to detect COVID-19 and the termination of mandatory Zika virus testing, which was partially offset by robust sales of blood typing solutions. Excluding these 2 items, the business unit declined by 3.5% at constant currency in Q3 year-to-date 2022. As already mentioned, these 2 items impacted consolidated gross margins by 250 basis points in Q3 year-to-date '22. This, together with some country mix and pricing, were partially offset by growth in the Chinese market and higher donation volumes, resulting in 35% growth in China year-to-date 2022.

Blood Typing Solutions division recorded a robust growth of 20% supported by solid performance across EMEA and U.S. regions. And a stronger GelCard sales in Eastern Europe. As well as growth in China and rest of Asia Pacific due to increases in donations and sales of GelCards as well as instruments.

Recombinant proteins declined primarily resulting from the joint business collaboration on a new R&D project.

Regarding Bio Supplies, reported significant revenue growth in the third quarter, led by Bio Supplies Diagnostic supported by plasma for diagnostic, cell media and serum, as well as with acquisitions of Access Biologicals.

Bio Supplies Biopharma declined due to lower sales of non-therapeutic use albumin and Fraction V, which were partially offset by cell culture media revenue resulting from the acquisition again of Access Biologicals.

And now, I'll give the floor to Steve with his closing remarks. Thank you.

Steven Francis Mayer
Executive Chairman

Thank you, Victor.

I'd like to conclude by reiterating a few points that we've already made, but I think bear repeating. And to be clear, my management style is to keep returning to the most important priorities in the business, both those that make us strong and those that need changing in order to ensure that our organizational and business priorities are absolutely clear and are driven to and then beyond the finish line.

The Grifols Board of Directors asked me to join the company as Executive Chairman in order to enhance operational execution, financial discipline, business performance and shareholder value. We are going to do so initially by prioritizing operating efficiency and cost reduction throughout the organization, especially but not only in the cost per liter of plasma by the improvement of cash flow and by debt reduction. These initiatives are already underway.

Standing back from the know, I am absolutely certain that the fundamentals of our business and our strategy are strong and that we are well positioned to capitalize on our highly valuable assets and platform for years to come. I I'll be working closely with the entire management team to help Grifols focus on its key priorities and achieve its goals. We are creating a cultural performance and accountability, and to be crystal clear, I will be accountable for delivery, period.

Recapping what you've heard about our recent business results, Plasma Collections have grown by 25% over the previous year, which in turn is underpinning strong sales growth in the second half of 2022 and onwards. The market remains strong, and we aim to continue this momentum into the future. We're laser-focused on driving cost per liter down further.

Donor compensation per liter has declined by more than 15% since its peak in July 2022, and our objective is to realize further cost per liter decreases through a combination of continued donor fee management, operating leverage as higher volumes absorb fixed costs, and meaningful reductions in fixed and semi-fixed cost per liter such as labor and occupancy costs.

We call that characteristic of our industry, these lower costs will in general be recognized in our operating results 6 to 9 months after they are realized. We are also on track to meet our financial commitments for the full year 2022. We expect global revenues to finish the year in the EUR 5.8 billion to EUR 6 billion range, including Biotest, for about 7 months of the year.

Adjusted EBITDA margin for the full year is expected to remain in the 20% to 21% range for the reasons we've discussed. And with additional operating leverage, we anticipate margin expansion for 2023. Our leverage ratio was expected to decline to about 7.1x by year-end, a significant drop from the 9x reported just 6 months ago.

Also, keep in mind that this leverage ratio does not include any pro forma results related to the Biotest transaction. As you know, we forecast about EUR 60 million of synergies between Biotest and Grifols. None of these synergies are included in the forecast ratio I just cited, and none of the deleveraging alternatives we are considering are included in that ratio either.

As mentioned, the entire executive team is focused, and I mean focused, on accelerating the execution of the company's operating plan, on operational excellence, on cash flow improvement and debt reduction, and ultimately, on increasing value for all shareholders. We look forward to communicating with you more frequently and transparently, including the quarterly earnings reports and calls. Thank you.

Question and Answer

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Thank you, Steve, and thank you all for your time. So now let's start. We will be pleased to take questions from the sell-side analysts that follow our company, that of Grifols. [Operator Instructions]

So let's start with Vineet Agrawal from Citi.

Vineet R Agrawal
Citigroup Inc., Research Division

Can you hear me?

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Yes.

Vineet R Agrawal
Citigroup Inc., Research Division

Great. So this is Vineet here from Citi, on behalf of Peter. 2 questions.

So first of all, on '23, can you give some preliminary thoughts around '23? And if the trends you're seeing persist, can you give us a sense of the scope of margin recovery you hope to see? Could it be 22% to 25% or better?

And second, how motivated are you to accelerate your deleveraging activities? Could we assume all options being considered, including collapsing the dual share class structure, monetizing your Shanghai RAAS stake, and/or doing something with Diagnostics?

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Vineet, I think your question, it was a bit difficult to hear you because -- maybe you were too close to the mic, but I think your first question was on the primary margin and the timing associated to that, is that correct?

Vineet R Agrawal
Citigroup Inc., Research Division

No. I was just asking if you can give some preliminary thoughts around the 2023 margin progression. Could we hope to see 22% to 25% margin or better than that?

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Sorry, Vineet. What was your second question?

Steven Francis Mayer
Executive Chairman

I think questions involved margin progression during 2023, which maybe, Alfredo, you can respond to? And the second half of the question had to do with deleveraging alternatives, which you mentioned a couple, which I can respond to.

Alfredo Arroyo Guerra
CFO & VP

So to your first question, the margin progression, my comment is the following. The worst is already behind, so by focusing on the lower cost per liter, as I already mentioned, we see a significant decline moving forward, but remember that it will take time to flow through the P&L based on our long inventory cycle. So that means that we'll see meaningful, I would say, gross margin improvement coming from a lower cost per liter more in the second half of next year, so backloaded.

On the additional OpEx savings, yes, no. We will capture those since the beginning of the year, so that will help to improve our gross margin. But also if I move back to the P&L, by increasing the share of subcu, which we will expect that will be meaningful next year, this will help us to improve the gross margin. Remember that there is a significant price gap between the regular IG and the subcu IG. So this is going to help quite a bit about gross margin also starting next year. So that's what I'm going to tell now based on the gross margin as well as EBITDA margin, so the worse is already behind.

Steven Francis Mayer
Executive Chairman

With respect to the deleveraging alternatives, we're going to wait until we have something to announce before we give any details. But I'll just broadly state that Grifols has an extremely valuable, I would say, irreplaceable group of assets globally. We believe that there are opportunities to capitalize on these to reduce leverage while continuing the overall long-term strategy that Grifols has.

With respect specifically, I think you asked about the consolidation of 2 classes of shares. We've already said that we think that the equity is meaningfully undervalued today. That applies to both classes and shares, so we're not looking to a capital increase or equity issuance in today's trading range. And that also applies to the consolidation of the 2 classes of shares as the stock price recovers to what we believe to be a better reflection of the value of Grifols. That will be one of the alternatives we consider.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Okay. Now let's move to James Gordon, JPMorgan.

James Daniel Gordon
JPMorgan Chase & Co, Research Division

James Gordon. One question was about the medium-term target. Last year, it was actually Biotest [indiscernible]

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

James, we cannot...

Alfredo Arroyo Guerra
CFO & VP

We can't hear you.

James Daniel Gordon
JPMorgan Chase & Co, Research Division

I was saying that last year, there were targets set in conjunction with the Biotest acquisition for revenues, EBITDA and leverage. More than EUR 7 billion revenues, EBITDA, EUR 2.8 billion, and leverage below 3.5x. I believe those targets were pushed out to 2025 at the CMD. So should we still think that those targets could be achieved in 2025, or are those targets under review? Might it take longer to get to those targets? So a review on where we are on the revenue, EBITDA and leverage targets in the medium term.

And the other question was just in terms of pipeline. So there were some previous plans in terms of investing in various pipeline projects, things like outside disease, et cetera. Are all those plans still going on, or might you change some of the pipeline priorities as well? Is the second question.

Alfredo Arroyo Guerra
CFO & VP

To the first question about the leverage, yes, by 2025, either and all will be a combination of organic and non-organic. Clearly, our target is to be below 4x. So that's -- also remember that we need to go to the market to the -- get markets to refinance a portion of our debt. So clearly, it's a must that to be at a very good, I would say, leverage ratio at that time through a combination of both.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

And James, can you please repeat the second one?

James Daniel Gordon

JPMorgan Chase & Co, Research Division

Sure. I'm sorry for the bad line.

The second question was, are all the previous pipeline plans -- pipeline investment plans still definitely going ahead? Or is Grifols also reviewing them? Could there be changes in terms of investment plans and pipeline?

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Very difficult to understand you, but I think you're asking about the pipeline?

James Daniel Gordon
JPMorgan Chase & Co, Research Division

That's correct.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Vic Grifols?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

The pipe -- around the pipeline?

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Yes.

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Okay. As we said in our Capital Markets Day back in July, we continue to believe very strong in the progress that we are doing, in the different projects that we are undergoing. Very clear for Biotest products, fibrinogen and IgM. They continue basically on track. Regarding the albumin liver disease continues on track as well. Secondary immunodeficiency for our IG products continue on track, and antithrombin III in sepsis as well continues on track. So overall, everything continues as we said, in our last Capital Markets Day.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Okay, thank you, Victor.

Now, Sarita Kapila from Morgan Stanley, please. Sarita?

Sarita Kapila
Morgan Stanley, Research Division

Just to understand how we should think about increasing competition in the alpha-1 space, so particularly from Inhibrx, following the FDA decision to grant accelerated approval and given that the data we've seen to date is quite encouraging?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Regarding alpha-1, this is a project that needs still time to arrive to the market, which is the case.

Regarding plasma products, as we have said today, for instance, we are continuously developing tools that can help our franchise to progress. In this case, it's the evolution of our AlphaID test. Now in this case, At Home profile so that patients can self-test and get the resource at home from these new tools. And we continue to develop as well some life cycle management formulations for the better convenience of our patients. So this is regarding alpha-1, how we see the landscape.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Thank you, Victor.

And now we have Guilherme Sampaio from CaixaBank Equities. Guilherme?

Guilherme Macedo Sampaio
Banco BPI, S.A., Research Division

Yes. Can you hear me?

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

We can.

Guilherme Macedo Sampaio
Banco BPI, S.A., Research Division

Yes. Yes. Okay. Perfect.

Okay. So one question regarding the Grifols process of classifying the stake of GIC and Biomat. How we are in this process, and whether are you still counting on this to your leverage target?

And then 2 small questions on the results. So if you could provide some details on Shanghai RAAS performance this quarter? And if you could provide some color the FX impact on quarter-on-quarter net evolution?

Alfredo Arroyo Guerra
CFO & VP

Okay.

Regarding your question of GIC, let me remind you that the aim of both parties and the rationale had been always and is still that this is a financial instrument, which is an equity. So both parties, this is the understanding of the parties at the time of the agreement.

As you all know, afterwards, the auditors, KPMG, they have some, I would say, some inside talking. And finally, they came back with -- that applying the accounting rule that this is a debt. The agreement is not expected to be modified in the short term. However still, the door is open. So this is really where we are. But remember this is a 20 years, I would say, term. So now it's hard to get, I would say, a debt for 20 years. So as you can imagine, this is real equity or quasi equity. So that's -- as I said, that is not on the table for us.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Yes. And then on the FX impact?

Alfredo Arroyo Guerra
CFO & VP

The FX impact, overall, yes. This year is going to be close to EUR 100 million at the EBITDA level because there is a significant dollar revaluation, especially versus Europe. And since most of our revenues and most of our EBITDA is dollar driven, we're expecting and it's already bringing by the end of September, EUR 74 million of positive FX. By the year end, expected to be -- if the dollar trend remained the same, around EUR 100 million. So very positive this year. And for the next year, if it continues at a similar level, we have also -- we see also a positive impact. Less than this year, but positive indeed.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Thank you, Alfredo.

Emily Field from Barclays?

Emily Field
Barclays Bank PLC, Research Division

Just a couple. Just on the divestitures point, is there anything that is off the table? Because obviously, between Diagnostics and Shanghai RAAS, I know that was kind of asked earlier, but there's some complexity. So I just kind of was wondering as sort of anything on the table if the satisfactory price can be obtained?

And then secondarily, you mentioned in the prepared remarks a couple of times about fixed and semi-fixed costs. I believe the company commented a few years ago about the split between fixed and variable costs, and how that -- and how that could be managed in the event of emerging competition. Could you just give us an update on how you see that split between fixed and variable costs? And how much cost you would be able to shift in the event of emerging competition?

Alfredo Arroyo Guerra
CFO & VP

So to the proportion of the fixed and variable cost, a significant component, obviously, is the labor cost that overall accounts for near 50%, let's say, 45% of our debt total cost. Some of the cost -- those costs are, I would say, yes, variable, because you need certain people to run manufacturing plants, you need certain people to run operations and some in the back office. But clearly, there is a room for improvement, and the team up to now are moving forward is going to keep working on ripping off some of those savings. There are some low-hanging fruit there, and both at the plasma cost side as well as the rest of the cost across the whole organization.

So clearly, there is -- there are some upsides, not only at Grifols side but also, as mentioned by Steve, at the Biotest level, there are some synergies that can be attached.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Yes. And maybe on the first part of Emily's question, Steve, maybe you can take this one?

Steven Francis Mayer
Executive Chairman

Well, I think the critical point with respect to what you described as divestitures, which I'm not sure I would employ that term, but we think we have this portfolio of irreplaceable assets. We also have a long-term strategy. And obviously, as with any company, we're going to try to optimize that portfolio of assets in order to achieve both the financial objective of deleveraging but also the long-term strategic goal of driving shareholder value in the long term.

And so when you say -- would you ask if there are sacred cows or if there is anything off the table, value aside, what's going to be off the table is something that we think would have a material negative impact on long-term strategic shareholder value. But we do believe that there are many different ways of achieving our strategic objectives consistent with evaluating these deleveraging alternatives.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Okay. Thank you, Steve.

We have next in the line of Tom Jones from Berenberg.

Thomas M. Jones
Joh. Berenberg, Gossler & Co. KG, Research Division

I have 2 questions, one for Alfredo and one for Steven, if that's all right.

Alfredo, just a quick housekeeping one. I was a bit surprised on the drop-through in Q3 between EBITDA and net income. Was that just a step-up in interest rates that cause that, or are there any significant large one-off items that affected Q3? I know the tax rate can bounce around and occasionally, you get a relatively large FX charge in there as well. So was there anything kind of a bit more one-off in nature that meant that the EBITDA number didn't quite drop through to the bottom line?

And then my second question for Steven. It's really a big picture one, really. You've obviously been on the Board quite a long time and followed this company in the industry for even longer than that. What would you say, in your words, is it that's in Grifols that excites you that you think we, as investors, miss? Investors do love to hate Grifols a bit then -- what is it that the market is missing, do you think?

And then maybe a sort of corollary to that, is it if could just click your fingers today and change one thing about Grifols, what would that be?

Steven Francis Mayer
Executive Chairman

Well, first, not to be contrary, but we don't take the view that the market is missing anything because we respect all of our shareholders, because we think they're owners of the business and the market is probably smarter than any of us individually. So we're not bemoaning the fact that the market has not rewarded Grifols over the last year or 2, okay? So our goal is to drive performance and then to make sure that we're transparent and communicative as we get into the market we'll need more of that performance.

So if I stood back and looked in the biggest picture at Grifols, I think it's a great industry which over time has proved to have a lot of resiliency and growth characteristics. And globally, I think that growth will continue with a high degree of operating leverage, and I think a return to the margin structure that prevailed prior to the pandemic.

Clearly, at Grifols, there has been a maybe -- maybe not as much focus on execution and performance, operational execution and performance as we might have had. I'm not pointing a finger to past, but that's what we're going to be laser focused on. So we do have a long-term strategy, but we'd also have a short to medium-term strategy and that short to medium strategy that's going to be very, very execution focused.

So if I could snap my fingers, I would advance 2, 3 years, and we would have a highly accountable, highly incented, highly performance-driven organization that was just really, really focused on execution and on delivery, and I think we need to re-instill that in the organization a bit. But when you look at the big picture and you look at the platform and the portfolio of assets that Grifols has and the long-term strategy, I'm extremely optimistic. That's why I stepped into this role.

Alfredo Arroyo Guerra
CFO & VP

Tom, to your first question, the drop in the EBITDA margin mainly is driven by lower Biopharma margin associated to higher plasma cost. Remember that the time lag between the plasma cost increase and the time that flows through the P&L. So now in the second half of the year, so including Q3 and Q4, we're going to see Biopharma margin decline due to the higher plasma cost.

To the net income amount, the lower -- sorry, I said lower EBITDA level. To the net income, the drop is due to additional financial expense. Remember, which is associated to the interest rates height. Despite the fact that we have 35% only floating debt, we had an impact, no doubt. And that impact, once the interest rate is announced, it takes around 2, 3 months to hit our P&L because that's -- we have the quarterly interest rates revisit. So that's why now we see in Q3 and also in Q4, we're going to see a higher financial expense. So that explain why the net profit for the Q3 is lower.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Okay. Thank you, Alfredo.

Now we are -- we have 3 more questions. So if you want to stay with us, we'll take these 3 and so to complete and to get the possibility to everybody.

So we have Rosie Turner from Jefferies.

Rosie Turner
Jefferies LLC, Research Division

Three left from me, please.

Just thinking about your plasma collection volumes, up 25%. I noticed that 42 weeks of the year, so does that include Mexico and the border reopening? And kind of are you able to approximate kind of how much of that is Mexico versus U.S. itself?

Then following up on Alpha-1 competition, I just -- can we just recap the level of penetration, I think, is it 70% of patients currently going underdiagnosed?

And then finally, just on that competition theme, just checking, we're still not seeing any impact from the anti-FcRn competition in myasthenia gravis. Am I correct there?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Okay. I take the question on alpha-1. If I understood correctly, is the level of diagnosis of the disease, what we think is the rate today? It's 90% of the potential patients are being not -- under diagnosed. And we hope that with, again, this enhanced tool with the diagnostic Alpha-1 ID At Home test there we can improve the level of diagnosis. I think this was the question regarding alpha-1.

And the other one is FcRn competition in myasthenia, where for Grifols, myasthenia accounts, I think, only 3% of our revenues today. We are not highly worried about that as we don't depend much on that. And we will see the progress of these new products and we will compete with our franchise, but it's not a big threat for Grifols in this indication.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Thank you. And on the Mexican?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Well, the Mexican, since September that now, we can operate regularly our centers. For the border centers, we are seeing an accelerated return of these donors to our network. And we are seeing every other week a move, a progression on the level of volume being collected at those centers. And as you know, in pre-pandemic levels, those centers were roughly collecting around 1 million liters. And now we are in this ramp up, and we are seeing the trend at some point we will hit this level of 1 million liters for those centers.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Okay, thank you.

And Julien Dormois from BNP.

Julien Dormois
BNP Paribas Exane, Research Division

And I'm sorry, I have 3 questions. One for Steve, one for Victor, one for Alfredo, if that's okay.

The one for Steve is that you made it clear during the call that one of your focus is to return to pre-COVID margin levels or close to that. But do you plan to provide margin targets for the period 2023, 2025? Because over time, there's been some misunderstanding between Grifols and the investment community and some disappointments on profitability. So do you plan to provide key targets for us to build our models?

For Victor, please, on the penetration for Xembify. Could you help us understand what you would do differently going forward to boost the penetration of this highly profitable product? Because it's been on the market for 3 years, so what can you do differently going forward in order to boost the penetration?

And the last question for Alfredo is a housekeeping on net financial cost, and following up on Tom's question. I think you had EUR 200 million in net financial costs in the first half of this year, is EUR 400 million as net financial cost for full year 2023 a good run rate? Or could it be higher than this?

Steven Francis Mayer
Executive Chairman

Well, let me start by addressing the first point, which had to do with whether we're going to provide guidance in terms of EBITDA margins.

Look, we're obviously in a somewhat turbulent environment. Macroeconomically in terms of other factors that will impact those margins, such as synergy, the Biotests, such as the ability to continue to drive down cost per liter of plasma and when those costs will be realized through the income statement through the decapitalization into inventory initially. And the long inventory cycle, some of the other cost reductions that we're planning.

The -- when exactly the new Biotest proteins will be approved and commercialized, even factors like inflation globally. So I think for us to provide long-term EBITDA margin guidance is -- would not be prudent right now. I think we'll revisit the question at least for 2023 in the coming few weeks or months. But at the moment, we -- I don't think we'll be giving any kind of precise guidance beyond '23 -- 2023 and even for 2023, we're asking to be a little bit patient because there are a lot of factors that are impacting it.

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Okay, thank you, Steve.

On the question regarding Xembify franchise. As you know, we -- unfortunately, at the launch of this new product coincided exactly with the pandemic period. So during the fiscal year, so of its launch has been very challenging, not being able to be present at hospitals and meet the customers and so on. Said that, and it's progressing nicely, the penetration of our product. The main characteristic that probably gives a competitive advantage is the tolerability of the product for our patients. This is very well received by those patients, of course. And we are progressing nicely.

The weight of our subcutaneous sales over the total IG is continuing to grow. Now we are in the range of 3%, and we are targeting to move that to a 5% proportion of IG sales. And the mid future, we are developing the secondary indication for that franchise that will further improve the growth pace of this nice product.

Alfredo Arroyo Guerra
CFO & VP

And then Alfredo -- regarding the financial expense, I'm talking about the interest because within the financial spend, there are deferred financial costs, there are FX, but just purely focused on the interest expense associated to our debt. Our quarterly run rate for this year is around EUR 75 million and expected to grow, as I mentioned, because the impact in our accounts will be backloaded because the timing of the interest rate hikes, so expected that the quarterly interest expense run rate will be around EUR 100 million.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer

Okay. Thank you.

And we have Alvaro Lenze from Alantra.

Alvaro Lenze Julia
Alantra Equities Sociedad de Valores, S.A., Research Division

I think that having this increased communication from the leadership is very welcome.

Three questions. The first one is you have announced several management changes over the last couple of months. Whether you are now happy with the team as it is right now, or we should expect any additional appointments?

Second question is on cost cutting, whether you could quantify how much cost cutting you have identified, and how much would you need to invest to achieve this cost cutting or if you are still working on these calculations? And if you're still working, whether you will provide some specific guidance on cost cutting once you have the plans ready?

And the last question more philosophically on leverage. You have historically targeted 4x net debt to EBITDA as your long-term goal, whether this could be rethought? I know that there's still a long way to go to bring leverage down to 4x, but whether you could change this as a long-term target?

Alfredo Arroyo Guerra
CFO & VP

Victor?

Victor Grifols
Chief Executive Officer of Grifols S.A., President of Grifols S.A and Director

Thank you, Alvaro, for your questions. I will probably take the sales part of your question, and then maybe Alfredo can complement.

During the pandemic, and we have been announcing that and communicating that. We have gone through several kind of wide range of improvements of the operations of the company. We have closed the business units that were not profitable or were not core anymore for us. In the case of [metastasis] business line, in blood banks, in the Diagnostic division as well and certain hospital division assets, now, no longer Hospital division is being reported isolated. We have closed the facilities. We have gone to the fit-for-growth process in -- across the world. So many, many things to improve the operations of the company. The same for R&D. We have prioritized or stopped and canceled some R&D projects as well. And subsequent to that, the final move, as announced at the last Capital Markets Day was the reorganization of the company.

Now fully accountable business units, and we needed specific presidents to run those business units. Now we have Pia on board and Jordi on board. And with that, we feel that all these kind of reorganization has been completed with those 2 appointments. And now, the organization is fully at speed with all the structure and all the talent in place to develop further operational improvements and to drive all what we have been talking during this, our call about improving the business overall.

Alfredo Arroyo Guerra
CFO & VP

Okay. To your -- couple questions, first, cost cutting. Here, I will address Steve initial comments. We're basically -- we're going to be focused on plasma cost, which is our main driver. It's where most of the costs are, I would say, in the company, including the company. So this is a various initiatives on driving down the plasma cost, point number one.

Point number two, the OpEx. Basically lower fixed cost as well as higher efficiency, delayering and many, I would say, initiatives now ongoing. Let me now provide you with some more color because now Steve just joined. And this is one of our top priorities which is in our table. So we are working on this, and we will provide you more color later on.

Regarding the leverage, as already mentioned, we will use whatever it takes, both organic and inorganic levers, to be at the target, I would say, financial discipline level, which is 4x or below. Especially, as I said, ahead of the 2025 debt -- partial debt refinancing.

Nuria Pascual Lapeña
VP of Corporate Treasury, Risk Management Investor Relation & Sustainability Officer
Okay. And with that, we've come to an end. Thank you, everybody, for joining. As always, the Investor Relations and Sustainability team will be happy to take any additional questions or any concerns or anywhere that -- how we can help. And speak to you all soon. Thank you.