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Grifols, S.A. BME:GRF

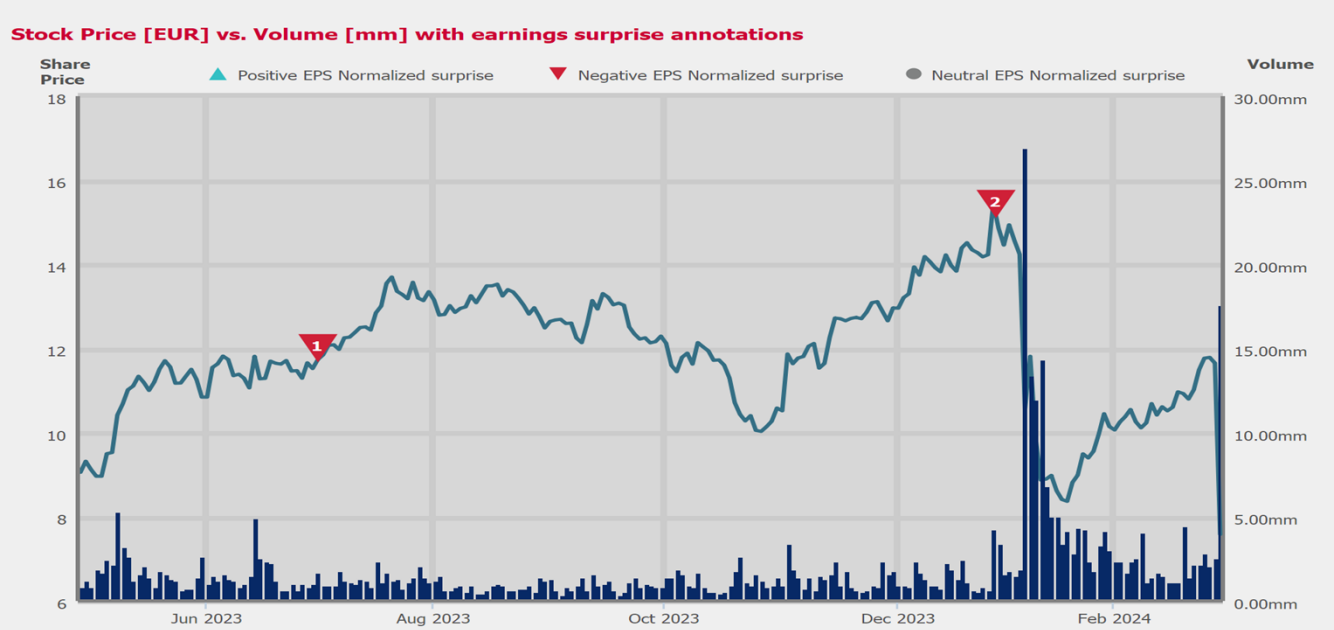
FQ4 2023 Earnings Call Transcripts

Thursday, February 29, 2024 1:30 PM GMT

S&P Global Market Intelligence Estimates

	-FQ4 2023-			-FQ1 2024-	-FY 2023-			-FY 2024-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS
EPS Normalized	0.19	NA	NA	0.14	0.54	0.34	▼ (37.04 %)	0.97
Revenue (mm)	1756.56	1769.55	▲ 0.74	1653.31	6614.43	6591.98	▼ (0.34 %)	7085.29

Currency: EUR
Consensus as of Mar-01-2024 7:28 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ1 2023	0.07	NA	NA
FQ2 2023	0.13	0.09	▼ (30.77 %)
FQ3 2023	0.13	NA	NA
FQ4 2023	0.19	NA	NA

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Presentation

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

Hello, everyone, and welcome to the Grifols Year-end 2023 Conference Call. Thank you very much for taking the time to join us today.

This is Nuria Pascual, Investor Relations and Sustainability Officer. And I'm joined by Thomas Glanzmann, our Executive Chairman and CEO; Víctor Grifols Deu, Chief Operating Officer; and Alfredo Arroyo, CFO.

This call will last about 60 minutes. There will be a presentation of approximately 30 minutes, followed by a Q&A session. [Operator Instructions] As a reminder: This call is being recorded. The materials for the call are on the investor relations website at grifols.com. And the transcript and webcast replay of the call will also be available on the investor relations website within 24 hours after the end of the conference call. Thank you.

Before we start, I would like to draw your attention to the forward-looking statement disclaimer on Slide 2 on the slide deck of our release. Forward-looking statements on the call are subject to substantial risks and uncertainties and speak only as of the call's original date, and we undertake no obligation to update or revise any statements.

Now I would like to turn the call over to Thomas Glanzmann.

Thomas H. Glanzmann
CEO & Executive Chairman

Thank you, Nuria. Good afternoon and morning to all on the call. Thank you for joining us today.

Before I start with my presentation, I would like to make you aware that we have filed the interim condensed consolidated financial statements earlier today that are prepared in accordance with the IFRS and approved by the Grifols Board of Directors. Grifols has received written confirmation from KPMG that it expects to complete its final set of internal procedures imminently; and issue its audit opinion by March 8, 2024, ahead of Spanish current legislation deadline. Consistent with prior years and confirmed by KPMG, they will issue a clean and unqualified audit opinion.

Now let us turn to our presentation. Víctor, Alfredo and I will explain how 2023 was a record-setting year and how we plan to accelerate profitable growth as we move into 2024.

Since my appointment as the Executive Chairman in February '23 and later as CEO, together with the leadership team, we at Grifols have been on a mission, a mission entirely dedicated to executing an ambitious plan to restore our financials, reshape the organization, strengthen our governance and prepare the company for the next chapter of growth. Now we are on the path for a sustainable and profitable growth journey, as we have addressed many of the challenges on both the operational and financial fronts while delivering on our commitments. The result: 2023 was a record year, but this is a journey and the turnaround with many pieces. We are committed and now progressing to realize the full potential value of the company.

Reflecting on the progress of the last 12 months. We started by strengthening and simplifying our corporate governance, along with building a best-in-class leadership team. Second, we executed a turnaround strategy that is leading to a solid financial profile and a strong operating base. Third, we have been elevating our innovation, digital and technology efforts, along with focusing on continuous improvements to become a market maker and shaper. In parallel, we have fostered a culture of excellence marked by a results-driven performance and continuous improvement with greater accountability. That being said, all that we've accomplished in 2023 does not mean we have arrived at our destination yet. Rather, it is a milestone in our ongoing journey to excel, and there is more to come.

The -- this February, we named Nacho Abio (sic) [Nacho Abia] as incoming Chief Executive Officer. This is the latest announcement as part of a long-term corporate governance plan put in place in 2022 to separate ownership from senior management. As part of this plan, I became the first non-Grifols family member that assumed the leadership and CEO role of the company. Personally and on behalf of the Board of Directors, I would like to express my deepest gratitude and appreciation to Raimon and Víctor not just for their commitment, leadership and valuable contribution to the growth of the company but also for having made the thoughtful decision to step out of their executive roles and, going forward, acting as proprietary directors of the Board.

I am also delighted to welcome our incoming Chief Executive Officer, Nacho Abia. Nacho brings a wealth of industry experience and a proven track record in operational success, which makes him the ideal leader to continue executing on the strategy we have initiated

and are implementing. He will assume his position on April 1. And I will continue as Executive Chairman, working hand-in-hand with Nacho, ensuring that Grifols realizes all its potential in a very important transitional chapter of the company. My Executive Chairman role will convert into a nonexecutive role in 2025, in line with good governance practice.

We have also assembled a team of leaders through new appointments in some key leadership functions, including Biopharma, innovation, digital, human resources and Bio Supplies. I'm sure Roland, Jörg, Miguel, Camille and Laura will be great additions that will boost and elevate their respective areas and complement the existing strong team of experienced Grifols leaders.

As part of our commitment and effort to have the best-in-class governance standards, we will continue to focus on our corporate governance and implement relevant improvements where necessary. We will simplify structures and we will not pursue any new related-party transactions. I also want to emphasize our continued commitment to enhancing our communication with the capital markets, which also has been a priority for us in '23.

Today, we present our full year financial and operating results, marking a year in which we not only met but exceeded the guidance we provided for '23. I am personally very proud to say that we have delivered on all the commitments we made. Not only was this very important for '23, but it will be equally important as we look ahead to '24. For '23, we have reported all-time-high revenues of EUR 6.6 billion, while we also delivered a significant EBITDA expansion, reaching EUR 1.47 billion, which represents a growth of 26.3% at constant currency. This exceeded our guidance and closed the year with an EBITDA margin of more than 26%.

As a testament to our operational and financial discipline, we have fully executed the operational improvement plan, yielding more than EUR 450 million in savings and transforming Grifols into a more efficient and cost-effective organization. Thanks to this plan, we are now seeing a positive read-through to margin expansion, a trend we expect to continue throughout '24.

Cash flow generation is one of our top priorities. Operating cash flow improved EUR 300 million throughout the year compared to '22. This rebound is expected to accelerate in '24 and onwards, as Alfredo will explain. Be assured that this is an area of significant focus of the company going forward, as we have work to do here, needless to say deleveraging remains core to our strategy, with our leverage ratio declining to 6.3x, driven by organic improvements from the 9x peak last year. Additionally, the proceeds from the sale of the 20% of Shanghai RAAS, a transaction which will close in the first half of '24, will be fully utilized to repay debt. The pro forma leverage ratio for the transaction stands at 5.4x in December '23, which supports our progress towards the 4x target.

During this past year, we also have put our focus on initiatives that will be critical to our growth trajectory: first, innovation, our engine for growth. We take great pride in the achievement of all our ambitious milestones for '23. Recently, we announced successful top line results of fibrinogen, which will be followed during the next months by the full data rollout. Another important project is the dosing of the second cohort of our Phase I/II study evaluating the first-in-human subcutaneous dosing options for patients [indiscernible] alpha-1 antitrypsin deficiency.

The second key initiative involves our strategic alliance with the Haier Group. This partnership expands our access to the albumin market and supports the growth of biopharmaceutical and diagnostic solutions in China. We also continue to see great progress in our Egypt and Canada projects. In Egypt, we are just about to open our 10th donor center, the halfway point to the planned network of 20 centers. Thanks to the expansion of centers and enthusiastic donor turnout, we are already collecting enough plasma to meet Egypt's immunoglobulin needs, a significant milestone in our efforts to help the country and region reach self-sufficiency in plasma-derived medicines.

Third, we have optimized and streamlined our U.S. plasma center network, resulting in improved labor productivity and increased yields per donation. We are very focused on further stepping up our efforts to be the leading in the industry in this area and are looking forward to launching new projects in the field. Fourth, we are and will continue to capitalize on data, digitalization and technology. This year, we established a center of excellence for artificial intelligence, which will play a pivotal role in advancing our initiatives across the company.

Having delivered on all our commitments and priorities, we have truly repositioned Grifols for a sustainable and profitable growth phase. This marks a new chapter in our journey, and we are very excited to have begun it. Before Víctor takes you through the details of the performance of our business units, I invite you to also take a moment to look at the annex of our presentation to review Grifols' comprehensive efforts in sustainability through '23, as we are proud to have been included in the world Dow sustainability index for the third consecutive year in a row.

Finally, I would like to conclude by expressing my deepest gratitude to the entire Grifols team for their hard work, passion and unwavering dedication to deliver 2023.

Víctor Grifols Deu

Director

Thank you, Thomas. Good afternoon or good morning to everyone, and thanks for joining us today.

Grifols revenue has reached a record high of EUR 6.6 billion, a 10.9% increase at constant currency, meeting the guidance set for the year. This achievement underscores our strong momentum, with revenues growing by nearly 35% in the last 2 years and positioning us to become a EUR 7 billion company revenues in 2024.

Supported by positive market dynamics, including strong demand, solid plasma supply, Grifols' Biopharma business was the main driver behind our performance, marking a total revenue growth of 13.3% at constant currency. This performance was also supported by an improved product mix, with our subcutaneous IG Xembify growing by close to 40%; a robust Europe and rest of the world; and a favorable price increase globally.

Now turning to Slide #10. Grifols Biopharma sustained the acceleration from previous quarters, delivering in Q4 a growth of 13% to close the year with an increase of 11.3%. All figures are at constant currency and excluding Biotest.

The IG franchise continued to be the main driver of our growth, representing 55% to 60% of our revenues, with a 2023 growth of 15.8% at constant currency. I will provide additional details of our IG franchise in the next slide. Albumin achieved a strong revenue growth year-to-date, delivering a 17% increase across all geographies, including higher demand and price increases in China. In fact, our Chinese market experienced a 40% growth.

Let me highlight the growth of alpha-1, which saw an increase of 2.4% in the fourth quarter of the year, indicating an improvement that we expect to continue in the upcoming quarters. The launch of the first direct-to-consumer buccal swab in the U.S. aimed to increase the diagnosis rate of alpha-1. This will continue backing our expansion for this franchise. On the other side, in Europe we have still seen in 2023 some impact by some recent industry dynamics there. Grifols obtained Prolastin 4- and 5-gram vials presentation approved in Europe, providing us an opportunity to increase patients and health care provider satisfaction and an overall improvement in the franchise performance as we launch these new vial sizes in 2024.

Additionally, I want to emphasize the strong performance of our most recently launched products such as fibrin sealant, thrombin and Tavlesse, which have shown substantial growth, respectively. Furthermore, hyperimmunes continue demonstrating positive progress. And all this has been partially offset by a decrease in demand on our factor VIII products.

Moving to Slide 11. Grifols continues increasing the value of its IG franchise with a strong strategy. The revenue trend of our IG IV and subcutaneous IG has been very positively throughout the year, [accumulating] with growth of 15.8% and 37.3% at constant currency, respectively, in year 2023. Immunoglobulin growth was driven by our flagship product Gamunex and now subcutaneous Xembify, supported by a strong underlying demand, including faster growth outside the U.S. due to improved plasma supply. We are also gradually transitioning to higher-yielding brands, IG brands, therefore optimizing our production efficiencies.

With IG standing as the standard of care in the industry, we remain focused on the immune deficiency market, strengthening our presence in the fast-growing primary and secondary immune deficiency markets while also maintaining our leadership in neurology and acute care. With nearly 40% growth in sales in 2023, we continue to build momentum with our subcutaneous brand Xembify, increasing market share in the U.S. space. We plan to further capitalize on this growth with increased demand from this year launches in Spain and Australia and the obtention of regulatory approvals in 13 European countries. We are preparing for additional launches in 2024 and 2025 backed on these approvals.

Now moving to Slide #12. Over the past year, Grifols has focused on growing its plasma supply with a robust, more efficient and diversified plasma center network. We delivered very positive metrics in 2023. Our plasma volume increased by over 10%, positioning the company to meet growing product demand. The implementation of the operational improvement plan yielded substantial savings, with the cost per liter of plasma decreasing by 22% compared to its peak in July 2022. As part of it, we increased our labor productivity by 32% versus year 2022, while manufacturing cost per liter decreased by 5% versus same period 2022.

We're implementing best-in-class practices to further improve efficiencies within our plasma centers. Along these lines, we rationalized our network of centers and closed/consolidated lower-performance centers, resulting in a more optimized network in the first part of the year. In addition to this, going forward, we are targeting continued operational efficiencies through our process optimization, streamlined operations and leaner processes. We also remained focused on employee and donor experiences. On the one hand, we improved employee recruitment and retention, decreasing by 22 -- by 20% the time to recruit and by 10% the turnover. On the other hand, we are in the process of further enhancing donor attraction and retention, providing a differentiated and personalized experience. In order to do this, we will heavily rely on data, digital and new technologies. Our new Chief Digital Information Officer, we are sure, will bring fresh ideas in this space for us.

All this was delivered during 2023, with great outcomes for us. Now as we enter into 2024, the initiatives to continue driving new improvements and efficiencies in our operations are nothing but expanding. Further optimization leveraging new technologies and process efficiencies are either being implemented as we speak and/or being pilot for a thorough assessment before its implementation. On one side, we have 2 parallel yield improvement initiatives, 1 on IgG yield optimization that aims to deliver a significant 6% better yield from the manufacturing processes. The other one is at the plasma collection side, where it's expected to improve average donation yield around 10%.

On the other side, we continue focus in expanding our improvements across Biopharma manufacturing operations. It is a holistic approach across all our manufacturing plants that covers areas such as material planning and plant scheduling, direct procurement, supply chain, product flows, et cetera. In this case, the expected outcome is a saving of current year run rate manufacturing expenses close to 8%.

Now in Slide 13. Innovation is one of our cornerstones of our future growth, and our pipeline includes a wide range of opportunities. Unlocking and accelerating these clinical trials will be instrumental to our success. And we believe Jörg's appointment as Chief Scientific Innovation Officer will be critical in this regard. In this slide, you can see our pipeline, which offers a strategic balance between risk and value and includes over 30 clinical trials spread across diverse phases. These trials are concentrated in 4 [core therapeutic] areas where the company has a competitive advantage.

I am proud to say that we have successfully met the 12 innovation milestones set for 2023; in some cases, milestones that are leading to launches and approvals in 2024 like Xembify bi-weekly dosing; Yimmugo in the U.S.; or Prolastin 4-, 5-gram vial sizes in Europe. Additionally, a few days ago, we announced positive results from Biotest Phase III clinical trial for fibrinogen concentrate, making a significant step in tricking -- in treating acquired fibrinogen deficiency. These position fibrinogen concentrate for regulatory approval process in Europe and in the U.S., which are expected to begin during Q4 this year. Once this happens, it will become the first fibrinogen concentrate approved for acquired fibrinogen deficiency in the U.S., tapping into a global estimated market value up to $800 million.

Biotest [advancements], including other innovations like Yimmugo and trimodulin, reinforce Grifols' position in the plasma-derived medicine field. These developments not only contribute to future financial performance on the back of the industry plasma economics concept but also offer promising -- offers promising treatments underpinning the company's commitment to addressing unmet medical needs through -- with our innovations.

As we did last year, we are making a new commitment to deliver on our [near-term] pipeline milestones. Number one, starting with our alpha-1 antitrypsin 15% subcutaneous study, we have our first patient in screening who will be moved from single to repeat dose. Number two, we completed enrollment of the PRECIOSA study in 2023. And we expect top line results in the first half of the year, with last patients finalizing treatment phase.

Number three, we are expecting that -- the preclinical studies of OSIG in dry eye disease, for which we currently have already initiated start-up activities with a contract research organization. Number four, for Biotest, Yimmugo, the BLA FDA approval is expected by June.

Number five, the approval of the bi-weekly Xembify study is expected in the second half of 2024 as we continue to advance our trial following the FDA submission completion in June 2023. Number six, on the GigaGen front, our project in hepatitis B has begun preclinical activities support the -- to support the IND submission for a Phase I study later in the year.

Number seven, on the albumin front, PRECIOSA top line results are expected in the second half of the year, with last patients finalizing the treatment phase. Number seven -- sorry. Number eight, for Gamunex in bags, progress is on track for conformance lot production in the second half of the year.

Number nine, following positive top line study results in February this year, 2024, we continue to advance with our fibrinogen trial for congenital and acquired deficiency. We expect MAA and BLA submissions in the second half of the year and the regulatory approval process in Europe and U.S. to begin in the fourth quarter. These milestones are testament to our commitment to increasing efforts to develop new products and indications, which we plan to continue accelerating through 2024 and beyond.

Now moving to Slide 16. Our Diagnostic revenues bounced back in the fourth quarter, increasing by 6.4% at constant currency, bringing our full year growth to 2.3% on a year-to-date basis.

As mentioned in previous quarters, our NAT technology was negatively impacted due to pricing concessions given in exchange for extending a large contract with a key customer of ours. However, strong revenue in the Asia Pacific and instrument sales in Japan and in the U.S. are progressing well and are contributing to try to mitigate this negative impact. Additionally, we achieved successful

tender wins across key regions while partnering with the Australian Red Cross to become the first facility in the world to operate a fully automated NAT testing facility.

In blood typing solutions, we are seeing a strong growth across the U.S., Argentina, Spain, Brazil and Saudi Arabia, for example. Key contracts are awarded with large GPOs, IDNs and commercial labs in the U.S. All that is very positive -- is very positively continuing to deliver market share gains for us in the blood typing space. Concurrently, we are expecting FDA approval for a new red blood cell and gel card highly automated manufacturing facility in San Diego. In recombinant proteins, we have signed a new 10-year supply agreement with an important partner for us.

Now moving to Bio Supplies. Bio Supplies reported a full year growth rate of 11.3% at constant currency. The main drivers of profitable growth in this business is a combination of higher demand from current customers, together with new customers being supplied with our existing products, plus the additional to our portfolio as a consequence of the Access Biologicals acquisition.

This leads me to talk about the milestones reached in 2023. We undertook a commercial consolidation focusing on target markets as well as an operational consolidations in terms of facilities in the U.S. as a consequence of a synergistic exercise by combining Access Biologicals and IBBI operations for this division. We look forward to leveraging these integrations and capturing the full potential of this high-margin business unit.

And now I will hand over it to Alfredo.

Alfredo Arroyo Guerra
CFO & VP

Thanks, Víctor. And good day to everyone.

Slide 19. As already mentioned, we have executed our transformational strategy, turning the company around in 2023 and setting the basis for [the robust] operational and financial performance in 2024 and onwards. In the following slides, I will detail how the company has achieved sustainable revenue growth, enhanced profitability, improved cash flow; and made significant progress in our deleveraging plans. I want to emphasize that we have met our revenue targets and exceeded our EBITDA expectations in 2023.

Slide 20. As you can see on the left-hand side of this chart, the significant sequential improvement in EBITDA was primarily driven by both gross margin and SGA. Gross margin improved by 570 basis points to 41.4%, while SG&A decreased as a percentage of sales by 220 basis points, excluding the restructuring charges related to the more than EUR 450 million annual savings.

Our adjusted EBITDA reached EUR 1.474 billion, exceeding guidance and increasing by 26.3% at constant currency compared to previous year. Adjusted EBITDA margin excluding Biotest stood at 24% for the full year; and at 26.1% in the fourth quarter, marking a significant improvement of 580 basis points compared to the same period in 2022.

The successful operational improvement plan drove the reduction of the cost per liter by 22% versus July 2022 peak that -- and this has been steadily reflected in our P&L considering the 9-month lag coming from our inventory cycle. Most of the savings from our plan will flow into the P&L in 2024.

Slide 21. Cash flow generation is a high priority for the company. As you can see in this graph, cash flow generation trended upward in 2023, driven by strong momentum across the business. We increased operating cash flow by close to EUR 300 million, excluding restructuring charge. Free cash flow accelerated in the second half of the year and is expected to further improve in the upcoming years. Going forward, we anticipate a significant increase in our capacity to generate cash. And this will be achieved by inventory optimization based on an improved balance sheet per liter approach, by EBITDA improvement and by CapEx normalization.

Slide 22. We continue to make solid progress in our deleveraging efforts, reducing our leverage ratio from 7.1x at the end of 2022 to 6.3x at the end of 2023. This reduction has been organically driven by EBITDA improvements, which remains the main pillar in our ongoing progress towards our 4x leverage target. Furthermore, considering the upcoming $1.8 billion cash proceeds from the Haier transaction that be -- that will be fully used to repay debt, our 2023 pro forma leverage ratio would have decreased to 5.4x at the year-end.

The company expects to address the 2025 maturities in the first half of 2024. And we'll seek to do these in an efficient manner taking into account both the planned disposal proceeds and the various other options available to us, including refinancing these maturities while remaining consistent with our deleveraging objectives. Regarding our liquidity position, at the year-end, our liquidity exceeds EUR 1.1 billion, including over EUR 500 million in cash, strong enough to support our growth.

Slide 23. We're expecting to see revenue growth of more than 7% at constant currency, driven by Biopharma which is estimated to grow in the 8% to 10% range at constant currency. Main contributors will be robust underlying demand; strategic pricing management; product mix, especially since our subcu will gain further traction; and continued expansion of growth products and market expansion.

For 2024, we expect EBITDA adjusted to reach more than EUR 1,800 million. Excluding Shanghai RAAS contribution of close to EUR 50 million in 2023, this implies a -- like-for-like an amount of more than EUR 1,850 million. [This represents] 27%, 28% margin, excluding Biotest. This improvement mainly reflects the positive impact of our operational saving plan considering the 9 months accounting lag of the plasma industry. This is expected to be partially offset by some commercial efforts that the company is strategically implementing to regain key market accounts. As we advance in 2024, we'll be in better position to update the guidance accordingly.

Now I hand over to Thomas for final remarks.

Thomas H. Glanzmann
CEO & Executive Chairman

Thank you, Alfredo.

As mentioned throughout this presentation, in '23, we closed a record year having delivered on all our commitments that now set us up well for a strong '24. We've strengthened our corporate governance, reinforced our execution and delivered on all our stated goals, thanks to our turnaround strategy. We are committed to create a sustainable, high-performance company with a culture that is focused on results and fosters continuous improvement and accountability while operating with the highest governance standards. Having focused on strengthening the underlying foundation of the company, we are now in a position to further improve our financials.

Equally important is also to accelerate the execution of the 5 strategic levers that will set us up for long-term growth and success while delivering to the expectations of all of our stakeholders. As you recall from previous presentations, the strategic drivers are, first, focus on core areas where we have true competitive advantage, Biopharma, diagnostics and Bio Supplies; second, continue to accelerate our innovation efforts by strengthening our plasma pipeline and expanding into non-plasma opportunities where we feel we are differentiated. To achieve these goals, we will leverage new technologies to expand our innovative ecosystem.

Third, strive to not only participate in the global market but to shape it. Our strategy involves focusing on the most promising commercial opportunities and actively seeking high-impact strategic partnership. Examples of this are Egypt, Canada and our strategic alliance with the Haier Group announced in -- at the end of last year. Partnering with Haier Group ensures that China remains central to our growth strategy. And it will be key to expand our commercial footprint, accelerate development of new products and broaden our portfolio.

Fourth, we will achieve best-in-class donor experience while digitizing processes and making our operations more efficient. This approach ensures our donors enjoy a more personalized, seamless and rewarding experience. Fifth, optimizing operations continuously lies at the heart of everything we do, and we will continue to pursue efficiency [to excel] our business and operations.

These 5 pillars must be underpinned by a world-class and performance-oriented team committed to fostering a culture of talent, development and accountability. Importantly, it must also be reinforced by a culture of delivering to commitments year after year while upholding the company's 115 years of integrity, high ethics and focus on sustainability. The end result will undoubtedly create significant value for all shareholders. With this in mind, I am confident that the progress we have made in '23 will be repeated and further improved in '24 and in the years to come.

Finally, I want to take this opportunity to say that I'm incredibly proud of our entire Grifols team. None of our achievements would have been possible without their dedication, relentless efforts and talent, which have been the bedrock of this record year.

I now turn it back to Nuria, who will open it up for questions. Thank you.

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

Thank you, Thomas.
And since -- we'll better start because we are a bit tight in terms of timing. Let's start.

Question and Answer

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

[Operator Instructions] So let's with Peter Verdult from Citi.

Peter Verdult
Citigroup Inc., Research Division

Pete Verdult, Citi. 2 questions, please. Thomas, a little bit unfair, but when can we be more confident the Spanish regulator is not going to escalate anything following the Gotham report? I know you responded to their questions, but it's clearly weighing on sentiment on the stock, so anything you can say there would be helpful. And then secondly, to Alfredo, just in terms of giving us some hard numbers or ballpark numbers on free cash flow expectations. I know you've given EBITDA guidance, but can we maybe just kind of push you to give us some sort of ballpark free cash flow expectations for 2024?

Thomas H. Glanzmann
CEO & Executive Chairman

Thank you, Peter. On the first one, we have responded in a timely and really complete fashion to all the questions that we received from the regulators; and they are now working and doing their work. And my assumption is that we will hear when they are ready.

Alfredo Arroyo Guerra
CFO & VP

Okay, to the second question of the free cash flow. We expected that -- for 2024 to generate additional free cash flow. And basically we are targeting to be slightly, I mean, below breakeven. The cash flow before the interest will increase significantly. And then we have the interest rate we are -- the interest rate. That tells you that our free cash flow will be around breakeven.

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

Thank you, Alfredo. And we have now Jaime Escribano from Banco Santander.

Jaime Escribano
Banco Santander, S.A., Research Division

So a couple of questions from my side as well. So on Shanghai RAAS, could you update us, where do you stand in the process? Have you finished the due diligence? And what is left for closing, and when could we expect the closing? And the second question would be in terms of a cost-saving plan. You -- have you found any more cost savings? Because I remember you -- in the last guidance, you were providing [EUR 400 million then EUR 450 million]. Is there any targets for 2024?

Thomas H. Glanzmann
CEO & Executive Chairman

Jaime, thank you for your questions. On Shanghai RAAS and Haier, the due diligence concluded today; and I'm pleased to say that the deal is moving forward towards closing. We're waiting for the regulatory approvals, but we're planning or targeting -- or I don't know. Closing will take place in the first half of 2024. And I want to reiterate that all proceeds will go to pay down our debt.

Víctor Grifols Deu
Director

Regarding the second question. The [indiscernible] operational improvement plan that was announced and execute during 2023, this is -- we consider this to be, let's say, closed. There is some inertia still there that is having, let's say, a positive trend, but [as I per said], the plan is closed. For instance, this inertia, we estimate that we may see some improvement still in the plasma cost per liter, not of course the 22% that we have experienced during 2023 but just to see some positive inertia there. And what I would like -- based on this question, probably you have noticed that we are talking about some new initiatives that we are going to, yes, implement in -- or work and implementing in -- during 2024 that related to efficiencies. 2 of them related to yield; and another one, a new one in the Biopharma manufacturing operations, that we estimate will be around 8% of run rate cost savings.

Nuria Pascual Lapeña

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

Thank you, Víctor. From JPMorgan, we have James Gordon now.

James Daniel Gordon
JPMorgan Chase & Co, Research Division

James Gordon from JPMorgan. One question was just on the 2024 margin guide. So ex Biotest, you said 27% to 28%, but in 2023, pro forma was 28% to 29%, so just the reasons why, even with a higher top line and presumably significant operating leverage, the margin is actually down a little bit. Is some of that Shanghai RAAS going? Or I think you made a reference to increased commercial efforts. How much are you ramping up sales and marketing? And why exactly are you doing that now? I think there was a comment about having lost some accounts, so is it supply is now exceeding demand and you having to stimulate demand? So what the assumption is there on sales and marketing or any other factors on the margin -- well, just on the margin, [I've had] some questions about Biotest in terms of why does the company break out margin with and without Biotest. At what point do you think Biotest isn't going to be a drag on margins and you just have one overall margin?

And then the second question was just IG growth looks pretty strong; alpha-1, a bit less so. So what's the thinking there for 2024? Are you thinking you can sustain this level of IG growth? And do you think alpha-1 could accelerate? Are these temporary issues? [Or the reasons for it might be] quite a bit slower than IG in terms of its growth. Because I know that's a very profitable product.

Alfredo Arroyo Guerra
CFO & VP

[Okay]. So I'll take the first two. Thank you. The EBITDA margin in 2024, as I said, on one hand, will be positively impacted by the -- all the plasma cost savings that are already in the balance sheet, but these will be partially offset by commercial efforts. What does it mean? Basically additional marketing activity to fuel the growth of both IG and alpha-1. And at the same time, we, the company, is going to -- for selective key market accounts, we'll regain. We're going to regain those accounts that we lost in the year that we didn't have enough plasma. So that's why you see this slightly decline of the margin. On the second topic of Biotest, as I said last time, the Biotest will still be dilutive for the -- from the margin perspective until the year of '26, '27, when Biotest will launch the fibrinogen and -- right after the [trimodulin].

Víctor Grifols Deu
Director

Regarding the, let's say, commercial questions. First, on the IG franchise, regarding subcu, we are very confident. We are seeing continued great momentum for this franchise both in the U.S. and also in Europe. As we said, we are planning to launch new products in the countries that we got the approval during 2023, so good momentum for our Xembify product. Regarding the IV formulations, in the U.S. we are seeing a strong demand in the U.S. market. For instance, the year-to-date October data, public data, it's growing around 11%, so very strong growth. Said that, in this market, I think we are all repositioning. And some, let's say, healthy pricing environment in terms of competition, it's being out there, but I think it's very healthy. And we are all repositioning ourselves. And for U.S., in this case for the IV formulation, we continue to see a really strong momentum, a lot of underlying demand. And now that we have plasma and therefore product to deliver to those markets, we are meeting this strong demand in the U.S.

And for alpha-1, in -- outside U.S., or Europe, I should say, more precisely, we expect to rebound from the recent industry dynamics that have happened during 2023 coming from 2022. And we feel very, very confident that the new launches of the 4- and 5-gram vials will be, let's say, nothing but supportive of these expectations. And for the U.S., we are seeing a recovery. You have seen in Q4 2023 we have shown a growth in that franchise. We expect to continue to see good momentum, thanks to the alpha-1 buccal swab testing that we launched at the beginning of 2023. And at the same time, we are enhancing our direct-to-patient PROLASTIN DIRECT experience with our patients together with our partners in the field.

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

Okay, thank you. From Barclays, we have next in the list Charles Pitman.

Charles Pitman
Barclays Bank PLC, Research Division

Yes. So 2 questions from me. First one, just going back to free cash flow, I think, Alfredo, you said that you're targeting break-even free cash flow for this year, so just to try and square the circle on your expected net debt leverage target: If we're going to work back

to 4x expected level, given the 5.4x pro forma post Shanghai RAAS in FY '23, that suggests you need around 400 million to 500 million of free cash flow to pay down debt. Are you saying that that's the break-even level in order to meet your target? Or are you trying to suggest that, post interest, there will be no free cash flow to pay down debt? In which case, how should we think about reaching that 4x target including Shanghai RAAS impact?

And then just the second one for me is on AATD. I'd just be interested to hear how you're thinking about the potential risk from Inhibrx under Sanofi and maybe if you can just touch on how you expect the SPARTA trial to help to offset this potential risk.

Alfredo Arroyo Guerra
CFO & VP

Okay, on the free cash flow question, I reiterate that our target is to be around breakeven for this year. To your question of the target, we are -- organically speaking, our year-end estimate is to be between 4x and 4.5x. However, we are considering selectively other potential divestment. So organically, again, between 4x and 4.5x and then considering other disposals.

Víctor Grifols Deu
Director

Regarding the question on alpha-1. And it's we believe it is still clearly an underdiagnosed condition. We estimate that around 90% of those patients are not being diagnosed, therefore not served with a proper treatment, so -- and Grifols, as you know, it's kind of leading efforts constantly in this front. We have the health care professional test. And as I said earlier, we launched the buccal swab; and it's already in the U.S. and it's very good progression. So testing, we think it's a great tool to continue developing this market; and then on -- in addition to that, again the 4-, 5-gram vials. We think it's a great tool to defend our franchise. SPARTA, as was indicated, it's an efficacy trial that will position Grifols, if results are positive, with the only, let's say, product in the market with efficacy data, clearly being an advantage to compete in the market. And the additional tool that we are pursuing is to develop a more convenient formulation for patients which is a subcutaneous 15% alpha-1 product. We think, with all these, let's say, portfolio of initiatives, we feel very confident this franchise will be continuing -- contributing greatly to Grifols.

Thomas H. Glanzmann
CEO & Executive Chairman

Charles, we obviously [indiscernible] it's still early days, right? So we're -- I mean in addition to the fact that it is early days for them. And we are doing all of these things and accelerating things that Víctor just mentioned now. We feel very confident about the position for the alpha-1 franchise going forward.

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

From -- we have from Berenberg Tom Jones.

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

First one, just on the EBITDA guidance. I think there was a bit of debate this morning about kind of precisely what you meant by EUR 1.8 billion-plus. I guess the way I was thinking of it is I think that we should think of that EUR 1.8 billion number more as a floor rather than a target. I was just wondering if you were thinking kind of along the same lines. And then secondly, I just wanted to follow up on operating and free cash flow comments. I'm just struggling to see how you get from EUR 1.8 billion of EBITDA to 0 free cash flow. If you take off EUR 500 million, EUR 600 million for interest; another EUR 100 million or so for tax; another EUR 200 million, EUR 300 million for CapEx, there's still EUR 1 billion left, so where are you intending on that to go, particularly given your comments around improving inventories? I'm just struggling to kind of reconcile your comments here.

Alfredo Arroyo Guerra
CFO & VP

To the first question -- thanks, Tom. The EUR 1.8 billion, yes, I'm aligned with your comments. This is our floor. That's why we said plus. Remember, in 2023, we started about the same, EUR 1.4 billion-plus; and then we updated quarter by the quarter -- quarter-over-quarter, this guidance. And the EUR 50 million from Shanghai RAAS, remember that this is an accounting [stuff], but when you book this investment in assets held for sale, you cannot, I would say, consolidate the 26% on Shanghai RAAS profits. So that's point number one. Point number two, here it comes the inventory, okay; this year, as you saw, the inventory growth of more than 400 million. For this 2024, we expect it to be flattish. So that's this is one of the main levers to achieve close to breakeven at the free cash flow level.

Thomas H. Glanzmann
CEO & Executive Chairman

Just one addition to what Alfredo said. I think we are extremely focused on making sure we hit our commitments. Historically, this is going to be really key for us. And when we say it's a EUR 1.8 billion floor, obviously it is the floor. And as Alfredo said, we increased our forecast last year 3 times. And as we see the market, as we see the progression of the business, we will obviously also address the EBITDA as we go, but we're very, very focused on making sure that we deliver on the commitments that we give to you and the market.

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

Yes. Maybe I can just ask the cash flow question in a slightly different way. By -- what do you specifically mean by breakeven on a free cash flow, i.e., 0 cash flow? Or that free cash flow will be roughly the same as the EBITDA number. I'm still a bit puzzled about what appears to be the lack of any expectation for any free cash flow this year.

Alfredo Arroyo Guerra
CFO & VP

That means that if I -- if we think in terms of cash flow before interest, before interest rate, that means that it's going to be around [400-and-something], which basically is the interest expense that we expect, we estimate for this year, 2024, on the back of the paydown or the payoff of the 2025 maturities.

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

Okay, thank you. We have 4 questions more, so we'll try to accommodate even if we go a few more minutes above the 1-hour time line that we had. We have Bank of America Graham Parry.

Graham Glyn Charles Parry
BofA Securities, Research Division

So firstly, just again to clarify on the leverage target. You previously said to go less than 4x by the end of 2024, and you don't seem to specify [end] '24 anymore, so can you confirm if that is the leverage target for 12 months end of December this year? And then you just mentioned 4x to 4.5x organically, so I just want to check. Is that 4x to 4.5x by the end of this year? When you say organically, does that include the $1.8 billion coming in from Haier or exclude it? So that's question on leverage target.

And then secondly, on the auditing issue with KPMG and perhaps just any further clarity you can give us on why it's not ready to issue an audit opinion now. And Thomas, I just wanted to again clarify your statement at the beginning of the call when you said they will issue a clean and unqualified opinion. So is that a certainty? So do you have line of sight on that? And is there just some administrative issues that are stopping that actually being in your press release today or your audited accounts being published today.

Alfredo Arroyo Guerra
CFO & VP

Okay, for the first question, just to clarify. The -- our best estimate for the year-end is a leverage target between 4x and 4.5x. That includes the organic, I would say, deleverage coming from the EUR 1.8 billion-plus and also including the Shanghai RAAS cash proceeds. And when I said that, if we consider -- we are considering other potentially divestments. Right now we are working on that. This means that we may hit the 4x [or] below.

Thomas H. Glanzmann
CEO & Executive Chairman

On the second question, on KPMG. Yes, it is administrative matters that we're dealing with. And yes, they have confirmed that they will issue a clean and unqualified audit opinion.

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

Okay, from JB Capital, we have Joaquin Garcia-Quiros.

Joaquin Garcia-Quiros

JB Capital Markets, Sociedad de Valores, S.A., Research Division

I just wanted to know if there's going to be more investments left regarding the next level project for 2024. And then sorry to come back again to the free cash flow figure, but doing some numbers: You said that working capital is going to be relatively flat, so even taking into account 600 million in interest costs, [leases] and others, there's still 900 million left. Let's say 300 million or 400 million out from CapEx. It's still 500 million. Can we -- is there going to be a 500 million one-off cost or something that everyone is missing? If you can explain a bit on that.

Alfredo Arroyo Guerra
CFO & VP

Okay. So basically, this year, the profit of the group, as you know, is being EUR 50-something million and -- but it's been heavily hit by the restructuring costs of EUR 160 million, so that means in -- this year will not have any [major] restructuring cost, point number one. Point number two: So that means that, with EUR 1.8 billion, our bottom line is going to be like almost 10x, so that means that we're going to -- we have to pay much more taxes, many more taxes. So you add to this those numbers. Plus we have some additional CapEx commitment in -- for instance, in our Canada plan. When you add all of those numbers, that leads you to this break-even amount that I mentioned to you.

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

Okay. And from CaixaBank, we have Guilherme Sampaio.

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

So 2. The first one, can you be more precise in terms of what are your expectations regarding taxes payment and CapEx this year? And second question, it's the asset sales that you are considering. Are you talking about a single large deal or several smaller assets that you could sell?

Alfredo Arroyo Guerra
CFO & VP

I'll start for the second one. As I said, we will selectively identify from our balance sheet those assets that can be disposed, but -- so right now I cannot confirm it's going to be 1 or 2 transactions. We're working on it. On the tax side -- but taxes is going to be at least more than 100 million additional taxes. And the -- in the case of CapEx, we're going to see another additional 100 million, 150 million.

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

Okay. And this is probably our last question today, from Alantra Equities, Alvaro Lenze.

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

Just to clarify on the commercial efforts that you mentioned within the guidance, whether those 150 basis points of EBITDA margin are already included in the adjusted EBITDA guidance for the year; and also if this basically represents lowering prices. And how can these have ripple effects across the industry? I don't know if you could expect competitors to react to this commercial strategy and also become more aggressive on pricing. And then second question, just if you could give us a ballpark estimate of what the nonrecurring results will be in 2024 as a whole.

Alfredo Arroyo Guerra
CFO & VP

Okay, regarding this investment, it's a combination of 2 type of commercial investment. One, it's true that for certain key accounts, as I said, we are going to invest in pricing to regain those accounts. And then everybody knows that the U.S. market is obviously everybody want to be there, so on the times that we didn't have enough plasma, we lost some key accounts, so -- but now we're in the -- we are trying to regain those accounts. And then at the same time, as I said, additional marketing efforts to further increase the growth of alpha-1 and IG. And what was your second question? Say it again.

Alvaro Lenze Julia

Alantra Equities Sociedad de Valores, S.A., Research Division

The nonrecurring items for 2024, if you could provide some guidance on the restructuring, plus Biotest next level, plus whatever. What's the total number?

Alfredo Arroyo Guerra
CFO & VP

Yes. Biotest next level, the -- for this, 2024, we expect it to be around 30 million, 40 million. And then we expect that -- still on the back of those additional savings plans mentioned by Víctor, that we may have around another 50 million of cash-out items. And then the we -- on the back of this potential refinancing, we may also incur in additional transaction costs associated to the refinancing as well as the closing of the Shanghai RAAS transaction.

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

So 80 million in EBIT and then another extra maybe in the financials.

Alfredo Arroyo Guerra
CFO & VP

See like all-in, like, 150 million, including, again, transaction costs, restructuring costs and next level.

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

Okay, thank you all. Thank you for taking part and thank you all for your questions. As always, we remain at your disposal, IR team and the whole management team as well, should you have any additional questions. And with that, I think we can close.

Thomas?

Thomas H. Glanzmann
CEO & Executive Chairman
Thank you very much for dialing in today. And we look forward to seeing or hearing you at the next call. Thank you.