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OVERVIEW:

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PRESENTATION

Operator

Good afternoon, and welcome to the Hologic Fourth Quarter Fiscal 2023 Earnings Conference Call. My name is Cynthia, and I am your operator for today's call. Today's conference is being recorded. (Operator Instructions)

I would now like to introduce Ryan Simon, Vice President, Investor Relations, to begin the call. Please go ahead, sir.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Thank you, Cynthia. Good afternoon, and thank you for joining Hologic's Fourth Quarter Fiscal 2023 Earnings Call. With me today is Steve MacMillan, the company's Chairman, President and Chief Executive Officer. Karleen Oberton, our Chief Financial Officer, is currently on bereavement and will not be joining us today. Karleen is with family, and I will be covering for her on our call. Please join me in wishing Karleen and her family well.

Our fourth quarter press release is available now on the Investors section of our website. We will also post our prepared remarks to our website shortly after we deliver them as well as an updated corporate presentation, and a replay of this call will be available on our website for the next 30 days.

Before we begin, we would like to inform you that certain statements we make today will be forward-looking. These statements involve known and unknown risks and uncertainties that may cause actual results to differ materially from those expressed or implied. Such factors include those referenced in the safe harbor statement included in our earnings release and SEC filings.

Also during this call, we will discuss certain non-GAAP financial measures. A reconciliation to GAAP can be found in our earnings release. Two of these non-GAAP measures are: one, organic revenue, which we define as revenue excluding divested businesses and revenue from acquired businesses owned by Hologic for less than 1 year; and two, organic revenue, excluding COVID-19, which excludes COVID-19 assay revenue, revenue related to COVID-19 and sales from discontinued products in Diagnostics.

Finally, any percentage changes we discuss will be on a year-over-year basis and revenue growth rates will be in constant currency unless otherwise noted.

Now I'd like to turn the call over to Steve MacMillan, Hologic's CEO.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Thank you, Ryan, and good afternoon, everyone. And before I get started, I just want to do a quick shout out to Karleen and her family and let everybody know our thoughts and prayers are with her today. We are pleased to discuss Hologic's financial results for the fourth quarter of fiscal 2023.

Total revenue was $945.3 million, and non-GAAP earnings per share was $0.89. It was another strong quarter overall, with revenue finishing at the high end of our range and EPS exceeding our guidance. Our fourth quarter capped off a tremendous year where we continued our track record of success, strengthened our business and delivered on our commitments. For the full year, we posted $4.03 billion in revenue and non-GAAP EPS of $3.96.

In 2023, quite frankly, we delivered some pretty exceptional organic growth rates, which were far above our longer-term targets. At the start of the year, we committed to deliver low double-digit growth. across each division. In the end, we delivered more, growing annual organic revenue ex-COVID in the mid-teens at 15.6%, with every division growing north of 13% and international growth just above 20%.

Despite various macro challenges, like clockwork, we continued to deliver, raising our financial guidance throughout the year, and living up to our commitments. At the same time, our balance sheet remains incredibly strong, and we have the financial flexibility to grow our business for the long term. For fiscal '24, we are confident in our ability to deliver against our 5% to 7% ex-COVID long-term organic growth target even against significant comps, one less selling week and a challenging macro environment.

In fact, if we look at 2024 on an adjusted daily sales basis, our annual organic revenue growth rate, excluding COVID, is projected to be in the 6% to 8% range. Whether adjusting for selling days or not, we believe our results will truly stand out from the crowd as we progress throughout fiscal 2024, particularly following a year of almost 16% growth ex-COVID in 2023.

Before sharing more of our excitement for 2024, we will first reflect on our Q4 results. In Q4, we grew total organic revenue, excluding COVID, 16.7%, with double-digit growth in every division. We again delivered on our promises. At the division level, Breast Health grew 27.4% and driven primarily by the recovery in our gantry business. Interventional Breast also posted a strong quarter, growing in the low double digits. We are pleased the division's gantry recovery is tracking to our expectations following the industry's chip supply challenges.

Moving on to Diagnostics. Organic growth ex COVID was 10.2%, again, driven by our strong Molecular business. Organic Molecular Diagnostics ex COVID grew 15% for the quarter, driven once again by strong contributions from BV/CV, TV, M. gen and Biotheranostics. With fiscal 2023 revenue ex COVID at $1.48 billion, our Diagnostics business is over 40% larger than it was in 2019.

Even more impressive, our base Molecular business is now nearly 80%, 8-0 percent, larger than it was pre-pandemic. Molecular has grown through a combination of more than doubling our Panther install base, adding new menu, gaining new customers as well as acquisitions into adjacent markets. This transformation and durable performance speaks to the ongoing success of our growth strategy.

Rounding out the divisions, Surgical revenue, at over $600 million in fiscal '23, is now nearly 40% larger than what it was in 2019. In Q4, Surgical grew 10.6%, driven primarily by MyoSure and Fluent, both growing double digits. In addition, our laparoscopic portfolio also grew double digits, albeit smaller in dollars compared to MyoSure and Fluent. More importantly, we are pleased our laparoscopic portfolio continues to gain traction.

To close the overview of our quarterly results and fiscal 2023 highlights, our international business continued to be accretive to overall growth rates, growing north of 28% on an organic ex COVID basis in Q4. We expect international to continue to be a key part of our growth story.

Before moving on, we'd like to revisit and reinforce our capital allocation strategy. In short, our capital allocation strategy remains the same. We continue to prioritize M&A opportunities; and second, we consistently look to utilize cash towards share repurchases, and we continue to be patient.

Having said that, we have recently seen the opportunity to deploy our cash balance more significantly taking the following 4 actions: one, in Q4 2023, we deployed $238 million of capital to buy back 3.2 million shares; second, in our current fiscal Q1 2024, we have already repurchased another 2.2 million shares for $150 million; three, today, we announced an additional $500 million accelerated share repurchase program; and four, we recently paid down $250 million of higher variable interest rate debt. Ryan will expand on both the ASR and debt repayment in his remarks.

Looking back 4-plus years since the start of the pandemic, the biggest acquisition we have made is of ourselves. During this period, we deployed over $1.4 billion on M&A opportunities and nearly $2.3 billion on share repurchases, including our recent repurchases in Q1 2024. And today's ASR announcement will make that $2.8 billion. As you can see, we are very confident in our position for the years ahead.

Rounding out our capital allocation discussion, to ensure we are optimized for the future, we carefully evaluate our portfolio on an ongoing basis. As a result, as mentioned in our release, we have recently divested our small SSI ultrasound business. Shifting gears, as we have shared on prior calls, we have broadly transformed our business and strengthened our fundamentals. Quarter-by-quarter, year-by-year, with macro hurdles ever present, we continue to prove our strength.

Today, we are effectively a new Hologic, retooled and recapitalized with strong brands, wide moats, industry-leading margins and the strongest, deepest leadership team we've ever had. Hologic is a differentiated and more competitive company than at any time in our 38-year history. At our core, we are fundamentally guided by our purpose, passion and promise.

Our purpose, to enable healthier lives everywhere, every day. Our passion, to champion women's health globally. And our promise, The Science of Sure, to provide health care professionals with clinically differentiated high-quality products. Across each division, we have distinct advantages created by our unique focus on elevating women's health through innovative products and trailblazing social initiatives like the Hologic Global Women's Health Index.

We ultimately develop our leading positions by leaning into our purpose and proactively meeting our customers' and patients' needs. We will highlight 3 examples today. First, we are not only leaders in women's health, but we are also sector leaders in workflow automation. Our customers continue to deal with challenges, sourcing technicians and the persistent pressure to efficiently manage costs.

As a result, user-friendly systems and efficient workflow solutions are at the top of our customers' expectations. From our Panther instrument to our Brevera breast biopsy and Fluent systems, to name only a few, each product is designed to transform manual labor-intensive cumbersome processes into easy-to-use, dependable and efficient workflows.

Second, the massive footprint and sheer size of our install bases in Diagnostics and Breast Health provide a strong foundation in today's world. With more than 3,260 Panther instruments installed worldwide and over 10,000 mammography systems installed across the U.S., we have the opportunity to be integral partners with the laboratories, hospitals and screening centers we support.

For Panther, as customers add more menu and drive incremental volume, our Molecular Diagnostics business continues to grow while also becoming more valuable to our customers and more deeply rooted in their operations. The same can be said for our Breast Health business.

Hologic is unique in our ability to support our customers and their patients at each step along the breast care continuum. We differentiate ourselves with our ecosystem of technologies that integrate across a patient's journey, creating a more comfortable patient experience, greater clinical confidence for practitioners and increased operational efficiencies for our customers.

Moving on to our third example, our long-standing brand leadership across multiple product lines in each division, which yields strong, stable margins and steady cash flow generation. We are innovators and leaders in breast and cervical cancer screening, STI testing, abnormal uterine bleeding treatment and fibroid removal. This is a significant statement given the strong competitors we face in each respective business.

Our diversified leadership and scale across our business lines support industry-leading margins and cash flow, and in turn, we have the ability to further invest and grow our business. Altogether, we are emerging as a premier growth company, differentiated and more competitive, delivering strong growth across each division and international. As the new, much stronger Hologic we are today, we consistently deliver and aim to continue to do so.

Turning our attention to 2024, I will touch on some of the high-level growth drivers in each business, and Ryan will finish the call with further detail related to next year's guidance. First, in Breast Health, we expect 2024 to be another strong year of growth. With our gantry backlog remaining elevated compared to historic levels, we have greater visibility into our pipeline, translating to higher confidence in future gantry sales, creating another exciting year for Breast Health.

In Diagnostics, as in recent years, Molecular will continue to drive growth for the division. We expect our large global Panther install base to continue to add new menu while also increasing volume for existing assays. In addition, our Biotheranostics business, which we acquired in 2021, is expected to continue delivering double-digit growth, being accretive even to our Molecular growth rate.

In 2023, Biotheranostics grew over 30%, and we are still in early innings growing the Breast Cancer Index test. BCI is still the only test recognized by NCCN guidelines and the American Society of Clinical Oncology to predict which patients are likely to benefit from extended adjuvant therapy beyond 5 years, yet another example of an innovative and differentiated product.

In Surgical, MyoSure, our Fluent system and our newer laparoscopic products that we acquired via Bolder and Acessa are projected to continue to drive growth. Internationally, Surgical also continues to shine. In 2023, our international Surgical growth rate was more than double the U.S. growth rate. Surgical is clearly emerging as a strong and profitable growth driver.

To conclude, entering 2024, we are a new and differentiated Hologic. We are bigger, stronger and more competitive than ever. Our leadership brands, growth drivers across all 3 divisions, durable margin profile and strong balance sheet will continue to power us forward. As we look ahead to 2024, we are poised to continue to grow and make an even bigger impact on women's health around the world.

With that, let me hand the call over to Ryan.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Thank you, Steve, and again, good afternoon, everyone. In my remarks today, I will touch on our fourth quarter financial results, recap our annual performance for certain items and end with our fiscal 2024 guidance for Q1 and the full year. We are pleased to close out fiscal 2023 with yet another strong quarter of growth and profitability.

In our fourth quarter, total revenue was $945.3 million, and again, we delivered double-digit organic revenue growth, growing 16.7% excluding the impact of COVID. In addition, our Q4 non-GAAP earnings per share were $0.89, growing 8.5% compared to the prior year despite significantly less COVID testing revenue. For the full year 2023, total revenue was $4.03 billion. Organic ex COVID revenue grew 15.6% and non-GAAP earnings per share were $3.96. These are exceptional results in what has been an unpredictable operating environment.

Now moving to a brief discussion of our divisional revenue. In Diagnostics, global revenue of $416.4 million declined 20.6%. However, excluding COVID assay and COVID-related revenues, the division grew 10.2% in the quarter. Performance was again led by Molecular Diagnostics growing 15% in the period ex COVID. For the year, Molecular posted very strong global growth of 18.9% ex COVID. As Steve highlighted, growth continues to be driven by increasing Panther utilization, turbocharged by a much larger install base and strong performance from Biotheranostics.

Moving next to our COVID results, which exceeded our previous guidance. COVID assay revenue in our fourth quarter was $21 million and COVID-related revenue, inclusive of a small amount of revenue from discontinued products and diagnostics, was $24 million. Staying in Diagnostics, our Cytology & Perinatal business increased 1.3% in our fourth quarter, a solid result following outsized growth in our preceding third quarter due to the timing of certain larger orders.

Moving to Breast Health. Total fourth quarter Breast Health revenue of $352.8 million increased 27.4%. The division's healthy bookings and elevated backlog provides us excellent visibility to meet customer needs and financial targets in fiscal '24 and beyond. Continuing next to Surgical, fourth quarter revenue of $148 million increased 10.6% compared to the prior year. Surgical's fourth quarter closes out a year in which the business grew a tremendous 15.8% organically, excluding the impact of Bolder in Q1. And finally, in our Skeletal business, fourth quarter revenue of $28 million was also strong, increasing 15.9%.

Now let's move on to the rest of the non-GAAP P&L for the fourth quarter. Gross margin of 60.4% was driven by strong performance in our base business. However, this result was partially depressed by certain elevated costs, including higher cost inventory from previously procured semiconductor chips.

Moving down the P&L, fourth quarter operating expenses of $303.7 million decreased approximately 8%. This decrease was driven by lower marketing spend in the period compared to the prior year, primarily due to the timing of expenses associated with our WTA partnership. Below operating income, other income represented a gain in our fiscal fourth quarter.

We benefited from higher interest rates on our cash balance, driving elevated levels of interest income. In addition, we realized gains on our interest rate hedge helping to lower interest expense for our floating rate debt. Finally, our tax rate in Q4 was 19.75% as expected.

Putting these pieces together, operating margin for Q4 came in at 28.3%, and net margin was 23.2%. As we have previously discussed, we expect operating margin to improve from this level throughout fiscal 2024. Finally, non-GAAP net income finished at $219.3 million and non-GAAP EPS was $0.89.

Moving on from the P&L. Cash flow from operations was $258.7 million in the fourth quarter, capping off a year in which we generated over $1 billion in operating cash flow. As Steve outlined, we were actively repurchasing our shares in Q4 '23 as well as the start of Q1 '24. For the full year 2023, we spent $500 million to repurchase 6.8 million shares. Even so, we ended the fourth quarter with $2.7 billion of cash on our balance sheet and a net leverage ratio of 0.1x.

Lastly, after the end of our fiscal fourth quarter, we completed one important capital market transaction and intend to enter into another. First, we repaid $250 million of floating rate debt associated with our credit agreement. This debt paydown helps to further protect our balance sheet against the risk of rising interest rates. And second, as Steve mentioned, we continue to bet on ourselves and announced a $500 million ASR, showcasing our resolute belief in the value of our business as we look to benefit from the stock markets' underappreciation of our intrinsic value.

Now let's move on to our non-GAAP financial guidance for the first quarter and full fiscal year. For our Q1, we are expecting total revenue in the range of $960 million to $985 million and EPS of $0.92 to $0.97. For the full year 2024, our guidance assumes revenue of $3.92 billion to $4.02 billion and EPS of $3.90 to $4.10.

As you reconcile our guidance to your models, we would like to call out 3 specific items pertaining to full year total revenue. One, the headwind of 4 less selling days in fiscal '24 compared to fiscal '23, which is about $40 million; two, the divestiture of the SSI ultrasound business, about a $20 million headwind; and three, the impact of FX, also about a $20 million headwind.

First, with respect to selling days, our fiscal '23 was a 53-week year. In fiscal '24, we have 4 less selling days compared to '23, specifically within Q1. We estimate the impact of the 4 less selling days to be a headwind of about 400 basis points to our Q1 results and more than 100 basis points for the full year.

Second, regarding the divestiture of the SSI ultrasound business. In the same way we treat revenue from our divested blood screening business, we will be removing ultrasound revenue from both the current and prior year when calculating our organic growth rates in fiscal '24. This ultrasound revenue was approximately $4.5 million in Q1 '23 and about $20 million for the full fiscal year. For fiscal '24, we expect immaterial remaining ultrasound revenue of less than $1 million per quarter.

And third, in terms of foreign exchange, we are assuming an FX tailwind of approximately $3 million for Q1 and a headwind of about $20 million for the full year. We anticipate the impact of the recently stronger U.S. dollar to be more acutely felt in the back half of our fiscal 2024.

Now turning to our divisional guidance. We expect that each base business will grow within our 5% to 7% framework for the full fiscal year at the midpoint. However, this may not be every division every quarter due to strong 2023 comps for certain businesses. Starting with core Diagnostics. We expect the business to grow within our 5% to 7% long-term targets for the full fiscal year '24, but likely below this level in Q1.

Our first quarter growth rates will be impacted not only by the 4 extra selling days in the prior year period, but also strong non-COVID respiratory comps. As we plan for fiscal '24, we are forecasting conservatively for menu items related to flu and RSV. At this point, we do not foresee a respiratory season in the first half of fiscal '24 that mirrors last year.

Closing out our non-COVID Diagnostics business, we expect Blood revenue of about $8 million in Q1 and about $30 million for the full year. In terms of COVID revenue, we expect COVID assay sales to be about $15 million in the first quarter of '24 and about $40 million for the full year. COVID-related items are expected to be about $30 million in the first quarter and about $105 million for the full year.

Moving to Breast Health. We expect fiscal '24 to showcase strong demand for our product portfolio as supply chain challenges abate. As a reminder, due to supply chain challenges in the prior year, our growth rate in fiscal Q1 will likely be above trend. Therefore, as we move throughout the year and comps normalize, growth rates may recede. However, total revenue should increase as we begin to work through our elevated backlog.

Finally, in Surgical, we expect growth rates within our long-term target of 5% to 7% for the full year, but below this level for Q1. In our first quarter of fiscal '24, Surgical will be impacted by 4 less selling days as well as the fact that we are lapping a pricing benefit from NovaSure's V5 product line extension.

Moving next to margins. We expect a cadence of improvement throughout fiscal '24 for both gross margin and operating margin as we work through higher cost during the year. For gross margin, we anticipate Q1 levels at approximately 60%, exiting the fiscal year in the low 60s. Similarly, our guidance assumes Q1 operating margins in the high 20s with a Q4 '24 exit rate in the low 30s.

Continuing to work down the P&L, we expect Q1 to represent our highest quarter of operating expense in fiscal '24. This is due to normal seasonal expenses associated with internal global sales meetings to kick off our fiscal year. For the balance of the year, we anticipate quarterly operating expense to be in line with the back half of our fiscal '23.

Below operating income, we estimate fiscal '24 other income net to be approximately neutral in Q1 and an expense of between $40 million to $60 million for the full year. Our guidance is based on an annual effective tax rate of approximately 19.75%, and diluted shares outstanding are expected to be approximately 239 million for the full year.

To conclude, our strong fourth quarter wrapped up a remarkable year for Hologic. As we move to our fiscal 2024, we remain focused on advancing women's health around the world while delivering on our promises and commitments to shareholders, employees, customers and patients. With that, we ask the operator to open the call for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We will take our first question from Puneet Souda with Leerink Partners.

Puneet Souda - *Leerink Partners LLC, Research Division - Senior MD of Life Science Tools and Diagnostics & Senior Research Analyst*

Thanks, Ryan, for the details there on financials. If I could ask 2 of my questions together, on -- we've been getting a number of questions around USPSTF. It's right around the corner. Could you update us on your thoughts for co-testing versus primary at this point? Any change in how it could turn out to be grade A versus grade B? And if -- wondering if you're incorporating any of that impact in your 2024 guide.

And then second part, Steve, is just with the FDA LDT regulation, do you think it changes the competitive landscape for Panther or for your approved diagnostic platforms?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Sure, Puneet, let me take those. First, USPSTF, we continue to think there's so much focus on this, it's, quite frankly, a very little impact to our business. I'd remind you back in 2018 when the first guidelines were being updated at that point in time, they came out, they were against co-testing. By the time, ultimately, they came out as official, co-testing was put back in.

We continue to feel very good about our business regardless of how they go. They also -- obviously, people have been focused on them for months and months, thinking they're coming every other day. We think it's a big ado about nothing, to be quite candid. I feel great about our business, feel great about the data on co-testing, and feel great that regardless of how they go, the clinicians are going to stick with our business, and there's going to be no change to our forecasts.

So regarding the LDT thing, I think, again, great question. It's part of where I view the strength of our business. First off, I think, again, that there's so much focus on what I call headline risks. To be clear, the LDT stuff won't come into effect probably until at least 2028. And there's going to be issues that are going to be battled between now and then, legislatively, everything else, so nothing that's going to impact the business over the next 3 years, probably the next 5.

At a bare minimum, however, we love where we're positioned in that most of us with our kitting and as you well know, from a Panther standpoint, it could create more opportunities. So the LDT thing probably creates more opportunity for us than it does risk. Having said that, we really just don't think much is going to happen on that over the next few years.

Operator

We will take our next question from Jack Meehan with Nephron.

Jack Meehan - *Nephron Research LLC - Research Analyst*

First, I hope Karleen and family are doing all right. And also, Steve, appreciate the commitment to the capital return here to shareholders. I think that's great. I was wondering if you -- just on the business -- okay. Can we talk about Panther? Now that we're at the end of the year, are there any updated utilization stats you can share for the system?

And second, the recent placement rates have slowed. I know there was some pull forward on placements that -- during the pandemic. I was just curious like how long you think this kind of lasts before hospitals and labs start expanding their fleets again?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. Great. I think the simplest thing on utilization is that our molecular business grew 18.9% last year, which is virtually all increased utilization on the Panthers, and we just love what we've done there. Clearly, as we said even at the start of last year, Panther placements for the next few years may be very small, and frankly, are almost immaterial to us growing the business.

Because at this point, there were so many machines put out there, as you know, from everybody, but I think especially from us. Now it's really ramping up the menu with our existing customers and an increased focus on expanding the fusion.

So I think the magic for us is now that we have so many Panthers in install, we're increasingly going back and getting the Fusion sidecar put on, which opens up the PCR assays. And I think we continue to see years and years of growth just even from the existing installed base as we're expanding the menu and putting more fusions out there. So Ryan, if you have anything you want to add?

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Yes. Jack, I'll add to that, that our growth, as we look forward, is not predicated so much on placing additional Panthers. It's really, what Steve mentioned, is placing more assays on the systems, expanding the Fusion footprint as well as growing the volumes of the assays adopted so far.

Operator

We will take our next question from Derik De Bruin with Bank of America.

Derik De Bruin - *BofA Securities, Research Division - MD of Equity Research*

Just some -- you commented on the pricing environment. Can you -- you (inaudible) what your sort of expectations are for pricing this year? And Ryan, just -- I know you said negative $40 million and negative $60 million expense for other, all-in, but what's the interest expense on that, just to clean the model?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes, I'll take the first part and then kick it over to Ryan. In terms of pricing, overall, we're assuming very modest pricing in our -- most of our gains really are volume, given that a lot of our contracts are already set with very little pricing increase. And I think it's where we're very proud of the fiscal discipline that we've been able to exert and then getting opportunistic pricing, or pricing really as -- as much mix as we launch new products, Derik, but very little of our growth is based on pricing at this point.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Yes. And on that second piece Derik, approximately $50 million in expense, in that number. When you're looking at it from a high level, like looking at '23 compared to of '24, the biggest difference there is we're assuming less cash on the balance sheet going forward. And -- but to answer your question, it will be $50 million on that interest expense.

Derik De Bruin - *BofA Securities, Research Division - MD of Equity Research*

And just one clarifying, if I can. The full ASR is embedded into the current guide for EPS.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Correct. Correct.

Operator

We'll take our next question from Patrick Donnelly with Citi.

Patrick Bernard Donnelly - *Citigroup Inc., Research Division - Senior Analyst*

Steve, maybe one on the Breast Health side. Obviously, you guys -- you had a bit of a backlog with the supply chain issues last year. Can you just talk about how you're working that down? What goes into the guide this year there?

And then a second one, just on the margin piece. I know we don't have Karleen, but maybe Ryan, just in terms of the moving pieces as you think about the '24 margin build, obviously, COVID coming down, some high-margin stuff, can you just talk about what you guys are doing to offset that and keep margins in moving the right direction?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Great. Thanks. First, in terms of the Breast Health business, I think we see clearly placing at least a double-digit increase in gantries this year, both domestically and internationally.

We really got going more in our second fiscal quarter last year, so especially this first quarter, we'll show much bigger growth for the Breast Health business. But I think we feel great about being able to continue to place the gantries in -- and just based on the backlog alone, let alone the additional customers we're winning.

Quick first crack at the margin piece, the way I think about it is, before Ryan comes in, is I think they will basically be lower in our first fiscal quarter and then growing through the year as we continue to bleed through the higher cost, especially chips, in gantries.

And we're also in the midst of relocating some of our -- basically our manufacturing for our Breast Health business from Connecticut down to Delaware. So at the current time, we've got double costs as we do that. And I think we've got great visibility that those gross and operating margins will be improved throughout the year. I don't know if you want to add more to that, Ryan.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Yes. Sure, Steve. So as we've previously called out, Q3, Q4, our expectation is that would be the trough with respect to operating margins. And as Steve mentioned, our expectation is to work up from there to the low 30s as an exit rate in 2024.

Steve pointed to the fact that we're working past and farther away from the highest cost chips. Our Breast business is also recovering, which is going to be a tailwind to margins as well. We did mention that we divested the SSI business, and that will also be a tailwind to margins as we go into 2024.

Operator

Our next question comes from Tejas Savant with Morgan Stanley.

Unidentified Analyst

Madison on for Tejas. Maybe just firstly, I was wondering if you could elaborate on how you're thinking about international growth for 2024. And I know you flagged the under-indexation to China as an advantage in the near term, but what's your combined exposure to China and the Middle East? And do any of that ongoing (inaudible) weigh on the demand throughout the latter part of -- in the Middle East region?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Sure. We have very little in the Middle East, and China is 2%. So between the 2, it's, call it, 2% to 3%, really. So we're -- I think -- we love that from the current environment. And as it relates to international overall, I think we've continued to see our international business as being clearly accretive to the growth rates of the company. And really, over the last number of years, it's been a double-digit grower and wouldn't count out that it couldn't do that again this year.

So we've strengthened our international businesses significantly over time. Our Breast Health business, getting stronger. Diagnostics has benefited hugely from all the additional Panther placements, so that's been growing tremendously internationally. And our Surgical business, after years of trying to work on reimbursement and getting products approved, is really also starting to take off internationally as we said, a real nice grower here over last year. So I think we see all 3 franchises being in very good shape to grow here in 2024.

Operator

We will take our next question from Vijay Kumar with Evercore.

Unidentified Analyst

This is Kevin on for Vijay. Just a clarifying question on the 4% to 7% base organic guidance for the full year. Does this include or exclude the 4 selling days impact, meaning excluding the impact would guide the 5% to 8%?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

You got it exactly. Yes. We factored that in. So that's why it's actually -- yes, it's 5% to a little north of 8%.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

And just a reminder, that is ex COVID.

Unidentified Analyst

Got it. And so just a follow-up. If the guide excludes days impact, why is the lower end...

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

No, it includes. It includes -- the 4% to 7% is including, just to clarify.

Unidentified Analyst

Got it. And just to follow up then, you also highlighted new share repurchasing in fiscal first quarter and an accelerated repurchase program. Is there a change in your capital allocation priorities? It seems like M&A was a focus in previous quarters.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. As we reiterated, we continue to focus on M&A. Right now, we just happen to think that one of the great acquisition opportunities is our own stock with where it's priced, and we're trying to send that signal very strongly. But we're continuing to look for external M&A as well. But we just love the position we're in. So it's not a change, it's just an extra opportunistic based on where the valuation of ourselves sits right now. Thanks, Kevin.

Operator

We will take our next question from Tim Daley with Wells Fargo.

Timothy Ian Daley - *Wells Fargo Securities, LLC, Research Division - Associate Analyst*

So Steve, following up on the Fusion comments you made to Jack's question, could you update us on the percent of the Panther install base currently Fusion-enabled at the end of fiscal year '23? And I guess -- or similarly, what were the Fusion sidecar placements in 2023?

Ryan M. Simon - *Hologic, Inc. - VP of IR*

What I'll comment on is the current attachment rate, and it's about 20% to the Panther install base.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes, and which is growing, but the way we look at it, it doesn't have to be 100% because the key is -- we think about it per customer, and so that each customer needs enough Fusions to be able to deliver what they need for their products. So we've seen very nice growth. We're not necessarily disclosing the exact numbers, but I really like the growth there.

Timothy Ian Daley - *Wells Fargo Securities, LLC, Research Division - Associate Analyst*

Okay. Got it. Then Breast, just talked about healthy bookings, elevated backlog, great visibility into '24. Just if you can help us, how much of the '24 Breast revenue expectations are currently covered in your backlog, or direct visibility via hard orders? Just curious on kind of the coverage rate for the year versus...

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Think about all of it, actually. If you look at it, as you'll see in the in the 10-K, that basically, we've got the orders in place for the year. Now we're going to continue to add orders to that for further out periods, but we're in great shape coming into the year.

Operator

We'll take our next question from Anthony Petrone with Mizuho Group.

Anthony Charles Petrone - *Mizuho Securities USA LLC, Research Division - MD & Senior Medical Devices, Diagnostics and Therapeutics Equity Research Analyst*

Also send condolences to Karleen and her family. Maybe the first one on Biotheranostics, just up 30% for the full year. and obviously, still in the early days as you mentioned, Steve, in your prepared comments. I'm just wondering when you think about, I guess, the synergy to the Breast Health business, you have 10,000 gantries out there, and I think there's 2 call points really for Biotheranostics, OB/GYN and then possibly a little bit in radiology, specifically.

But how should we be thinking about how many of your Breast Health install base users are currently using Biotheranostics? And how long will it take to sort of extract that entire synergy? And then specifically on margins, for Ryan, just when we -- that trajectory from high 20s in the first quarter to low 30s, is that linear? Are there certain inflection points throughout the year? If so, what are they? Is it operating leverage or more in pricing at the gross margin line?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Sure, Anthony, on the first one, it's a great question, and I don't have the specifics. I think our Biotheranostics sales team has been out there really focusing on a number of key docs. And so as they're building it up, I do think we're back to the early innings, still lots of opportunity to more broaden it with both our Breast Health as well as even our Diagnostics OB/GYN sales force. So still a lot of opportunity ahead to your point.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Yes. And Anthony, on the margins, as we've stated in the commentary, looking to work up from the high 20s to the low 30s through the course of the year. It should be a relatively consistent trajectory up to that range. As I mentioned on the prior question, Breast Health, recovery is a tailwind to the margins. The further we get away from the higher cost ships that are in our gantries as we progress throughout the year, that should be helpful as well. And again, the savings from SSI should be felt in the back half of the year as well.

Operator

We'll take our next question from Casey Woodring with JPMorgan.

Casey Rene Woodring - *JPMorgan Chase & Co, Research Division - Research Analyst*

Great. My condolences to Karleen and her family. So I just wanted to talk about the guide on Surgical business. So growth this year is going to be within the LRP range coming off a 16% organic comp in '23. Can you just talk about some of the growth drivers there? It sounds like international is a big piece of it. It sounds like pricing drove outperformance this year as well.

So can you just talk about how that business performed this year and the sustainability into next year? And then just one more quickly on the margin. So I think in '23, you baked in something around 200 to 250 basis points inflationary headwinds outside of that higher semi chip costs. How should we think about that dynamic here in '24?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Sure. On the guide on Surg business, I'd say we had everything working for us in 2023, including the NovaSure V5 launch that did have some pricing associated really. It showed up more as mix, but it was a higher-priced product. And then I think, frankly, procedures were pretty good.

But we fired across all cylinders, NovaSure, MyoSure, Fluent and then also Bolder and Acessa, and did it both domestically and internationally. I think as we go into next year, MyoSure and Fluent and Bolder and Acessa all continue to look as very good growth. NovaSure will probably be back to flattish to possibly down a touch. But internationally, I think, again, we see international being a solid double-digit grower in the year.

So feeling very, very good about our position. I would tell you one of the biggest surprises to me probably over my almost-decade now at Hologic has been the continued growth and the sheer scale of MyoSure as it continues to really grow the category. And if we think about TAM, the total available market, never realized how big it would be. And I think we're continuing to expand that market. So feeling very, very good about that.

I'll let Ryan take the second part of that. Everybody has decided I can't handle margin questions, so I'll go ahead and let Ryan go ahead and take them.

Ryan M. Simon - *Hologic, Inc. - VP of IR*

Yes. So I do want to clarify one comment that we made to Derik's question earlier. It is actually $50 million in income and $130 million in expense. So I had flip flopped that in the prior question. And again, with respect to margins, kind of just reiterating the comments that we've made here, it is an expectation that we are going from, again, the high 20s to the low 30s. The biggest impacting driver, again, is the Breast recovery and moving again farther away from the higher-priced chips.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes, I think that's what gives us such confidence in the gross margin expansion, to clarify that, is it is looking at the earned inventory that's sitting on our balance sheet that is just going to flow through on a -- effectively a first-in, first-out basis, so we can see those super high-priced chips that we got early and mid in the chip crisis bleeding through the product lines here in the first quarter. Really, by the first 2 quarters, most of that will be done, and it gives us great confidence as we continue to work through the year.

Operator

We will take our next question from Navann Ty with BNP Paribas.

Navann Ty Dietschi - *BNP Paribas Exane, Research Division - Analyst*

I just had a follow-up on the M&A. Curious to know whether Hologic came across interesting deals since August, and do you see a healthy amount of sub $1 billion deals?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Thanks, Navann. We continue to scour the landscape. The bankers have been all over the place with lots of ideas. We frankly are in that great position where we can be patient. If I still look at the landscape today, you've got a whole bunch of very smaller companies that went public in COVID time that are hemorrhaging cash and in bad shape.

And a lot of those still don't fit our criteria, so then we're looking at other things that may be a little bit more established. But the magic that we have for us right now is, given our growth rates, given our profitability, we've got a pretty tight hurdle rate that not a lot of things are making it to the top. So I wouldn't expect anything super imminent as we continue to look at the landscape.

Operator

We'll take our next question from Mike Matson with Needham & Company.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

So I want to ask one about the Breast business, specifically the gantries, I guess. During -- when you had all the kind of supply chain issues, you talked about the orders were coming in and remaining strong. And so -- and I know you've got a backlog now, but I guess what I'm wondering is how -- what is the ordering looking like? Because we have seen some kind of mix of signals out there about capital spending at the hospital level.

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. We continue to feel good about orders. Having been in this chair in a different company in the 2008, 2009 downturn, I'm always particularly attuned to trying to pay attention to concerns about capital freezes or capital tightening I think we just feel great about where we are, both in terms of the products we've already got the orders in as well as continuing to get new orders.

So we're booking candidly out beyond the current year at this stage, and just a lot of excitement still in our Breast Health business. I think what's hard for people to grasp is how much we've dramatically expanded our install base to where we're so strong in the U.S., and so many people just still coming to us. So really feeling very good about it.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. Got it. And then just on the international business, I mean, it's good to see the growth being so strong there. You sound pretty optimistic about the outlook. But I was wondering if you could maybe just talk about what's really driving the growth there? Is it expanding into new countries? Is it getting new products approved in your existing markets? Is it gaining share in existing markets? Is it maybe all of the above?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes, I'm glad you asked it. I think the magic for us is it is all of the above. It's this incredible diverse growth that, in very simple terms, if we actually do look almost country by country and franchise by franchise, and we were just with literally the sales leaders of each country for each franchise in Dubai a couple of weeks ago, so I'm coming fresh off looking at all of the plans.

If I look at the U.K., right, we have growth plans for Diagnostics. Not just Diagnostics, but Cytology as well as Molecular. In the U.K., we've got plans for the Breast Health business, and we have plans for Surgical. And it's bringing -- in the case of Surgical, it's bringing those products into these markets. It's getting the reimbursement. And it's just been a lot of nothing sexy and no one big driver, which I actually think creates the excitement.

And even as places like China have gotten a lot wonkier for most companies, because we're small there, we're not counting on that for our growth. We're getting it everywhere else. But -- it's not sexy, but it's incredibly effective that it's literally every -- almost every franchise in every geography. And these hundreds of thousands here and there as you keep adding them up, they become millions and millions and then tens of millions all through it. And I think it's creating this inexorable growth as we're bringing on new customers in each franchise. So thank you, Mike.

Operator

We will take our next question from Andrew Brackmann with William Blair.

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Andrew Frederick Brackmann - *William Blair & Company L.L.C., Research Division - Research Analyst*

Certainly sending condolences to Karleen here. I'll just stick to one on the innovation engine here. You guys have obviously done well sort of advancing the platforms through R&D and new launches, but how should we be thinking about major upgrades within the core franchises here over the next couple of years? Anything to call out there? Or should we be expecting, I guess, more singles and doubles moving forward?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Sure. I think we never want to overhype anything, but we've got some neat things coming both, particularly organically in the Breast Health business, Diagnostics, obviously, BV/CV is off to a tremendous start, and we're excited by that organic thing, and then working it out, but probably more in the continued singles, doubles category that hopefully, over time, those singles and doubles turn into triples.

I think if you look at Acessa and Bolder, right? They're growing very nicely. They're still very small. And so over time, I think the magic from where we sit today is we can see those franchises growing at above our company rate for the next 5-plus years, at least. And I think that's the magic of what we have going here.

So again, no one -- kind of back to Mike's question a little bit, no one product driving the growth. It's systematically coming across the product lines, and I think it creates a lot more durability. Thanks, Andrew.

Operator

And we will take our final question from Andrew Cooper with Raymond James.

Andrew Harris Cooper - *Raymond James & Associates, Inc., Research Division - Research Analyst*

A lot has already been asked, so maybe just one. You mentioned booking out already into next year on the gantry business. Just what is the typical kind of visibility you have at this point looking into the year relative to maybe where you sit now with this big backlog? In other words, how much bigger is that backlog than it typically would be?

Stephen P. MacMillan - *Hologic, Inc. - Chairman, CEO & President*

Yes. It's clearly peaked. I think we peaked up here in the last year, and now we will start to bleed that down. But we typically have reasonable visibility. By the way, it doesn't mean that an order can't be placed now that we wouldn't ship sometime in the next quarter or so. It all depends on how they're scheduled and everything else. But I think we feel really good about where we sit.

Operator

That concludes today's question-and-answer session, and this now concludes the Hologic Fourth Quarter Fiscal 2023 Earnings Conference Call. Have a good evening.
