Hologic Q3FY24 Financial Results

Earnings Conference Call Prepared Remarks

July 29,2024

Note: May Change Slightly When Delivered

Ryan M. Simon
VP, Investor Relations

Thank you, . Good afternoon, and thank you for joining Hologic's third quarter fiscal 2024 earnings call. With me today are Steve MacMillan, the company's Chairman, President and Chief Executive Officer; Karleen Oberton, our Chief Financial Officer; and Essex Mitchell, our Chief Operating Officer.

Our third 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 one year. And two, organic revenue excluding COVID-19, which further excludes COVID-19 assay revenue, other 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.

Steve MacMillan
Chairman, President & CEO

Thank you, Ryan, and good afternoon, everyone. We are pleased to discuss our financial results for the third quarter of fiscal 2024.

Total revenue for Q3 was $1.01 billion and non-GAAP earnings per share was $1.06, both again above the high end of our guidance. Importantly, we are excited that with COVID now mostly in the rear view mirror, our reported revenue has returned to growth.

Our strong performance goes beyond the top-line and shines throughout the P&L. For the quarter, we delivered a solid 31.2% operating margin and deployed $100 million during the quarter to repurchase 1.4 million shares. All in, the $1.06 in EPS translates to 14% growth on the bottom-line – a very strong result – and also very encouraging as we flip the script now to reported revenue and EPS growth again.

Looking back to the start of our fiscal year, we knew there were still certain questions on some investors' minds about the true strength and durability of our underlying business. These were questions that surfaced as we exited a period of uncertainty created by the pandemic, followed by the global chip shortage. While we and many long-term investors understood the power and potential of our transformed, much stronger business, we acknowledged that these unanswered questions created barriers for some of those newer to Hologic.

As usual, rather than rely on words, we knew it would be our performance that would emphatically answer these questions and clearly demonstrate that we are indeed a bigger, faster, stronger company than before the pandemic. Our third quarter performance should make this very clear.

In Q3, we bent the top-line curve to green after eleven quarters of COVID-driven declines. Our top-line reported revenue returned to growth at 3.1% versus last year. Organic ex-COVID we delivered healthy 5.8% growth. And we achieved these strong results on top of exceptionally strong 18.4% organic ex-COVID growth last year.

Turning to our themes for today:

First, we would like to recap our performance since the start of the fiscal year by answering 5 key questions which were on many investors' minds.

Second, we'll pass the call over to Essex, who will highlight certain overlooked elements of our broad based international growth, as well as provide an update on M&A activities.
On to our first theme – the Top 5 questions which have been out there:

1. Will Panther utilization continue to grow?
2. Will Breast Health return to full strength and maintain market leadership?
3. Will Hologic return to delivering industry-leading 30%-plus operating margins?
4. With a $2.4 billion dollar cash position, will Hologic be successful in deploying capital? And finally…
5. Can Hologic maintain its cervical cancer screening leadership if USPSTF issues an adverse cervical cancer screening guideline?

The short answer to all five is – without a doubt, YES. We will continue to thrive.

From here, we will take each question in order.

First, our molecular diagnostics business continues to deliver and is so much bigger and stronger than it was prior to the pandemic. Our global installed base of Panthers now exceeds 3300 and is rock solid. More importantly, our customers continue to praise and utilize our platform. Panther's superior workflow, automation, ease of use, and constantly expanding menu continues to drive demand and differentiate us in a competitive environment.

In quite simple terms, revenue per Panther and number of assays run per Panther continue to grow, with the simple metric being our Molecular Diagnostics growth rate.

In Q3, our molecular business excluding COVID grew 10.5%, on top of 12.9% growth in the prior year period. We've now delivered high-single to double-digit performance in 13 of the last 15 quarters. Quarter-after-quarter, year-over-year, we continue to deliver by expanding utilization, and our outlook remains bright.

Second, our breast health results continue to demonstrate a profound strength in breast cancer screening. Our gantry business is well on pace to fully recover from the chip shortage, and we continue to maintain our leadership position.

Our supply chain is much improved and now fortified from successfully navigating the chip-shortage experience. Over a decade from the initial launch of our breakthrough 3D mammography, customers still view Hologic as leaders in performance, including image quality and scan time, leaders in service, and leaders in customer satisfaction.

Letting the numbers speak for themselves, in Q3 we delivered 7.1% growth in Breast Health, on top of 27.5% growth in the prior year period. The business is more diverse than ever, and continuing to add in even more recurring revenue with our Endomagnetics acquisition.

Third, operating margins. As Karleen will share in more detail later, we delivered a 31.2% operating margin in our third quarter – a 230 basis point improvement from the prior year period, and an 80 basis point improvement sequentially.

At the highest level, we are now back to delivering pre-COVID margins, even with our International business being over 40% larger than it was in 2019. Consistent with our expectations, we recaptured our strong sector margin profile by maintaining focus on operational efficiency and moving past the amortization of higher priced chips purchased during the chip shortage.

Fourth, on capital deployment, our balance sheet and cash flow remain incredibly robust.

As announced last week, we recently closed the Endomagnetics acquisition – a transaction that we view as straight down the fairway in terms of execution within our broader M&A strategy. Overall, the deal is a prudent investment of capital that we expect to add revenue, margin and EPS accretion over time. Together, we have an incredible opportunity to improve interventional breast care for women.

On top of closing the Endomag deal, we continue to demonstrate that we are willing to bet on ourselves and repurchase shares. As a baseline, we are looking to offset dilution from our internal share plans. And from there, with our strong cash position, we look to layer on additional share repurchases. Fiscal year to date, we have repurchased 10.5 million shares for $750 million.

We plan to continue on our capital allocation path and fully intend for our deployment strategy to include both M&A and share repurchases.

And finally, before turning the call over to Essex – USPSTF. As we've done for nearly 30 years in cervical cancer screening, no matter the direction the USPSTF may take for its cervical cancer guidelines, we will navigate the landscape and remain strong.

Overall, we achieved our strong results by maintaining our long term focus and commitment to women's health. As we shared on our Q2 call, the strength of Hologic lies in the sum of our parts. We expect our results to continue to answer the call, and speak for themselves while we continue to demonstrate our durable strength quarter-after-quarter, year-over-year.

With that, I'll turn the call over to Essex to share insight on international growth drivers and more on Endomagnetics.

Essex Mitchell
COO

Thank you, Steve.

Overall, our third quarter performance speaks to the successful implementation of our growth strategy -- building multiple durable growth drivers into our franchises around the world.

Today, we'd like to quickly highlight three specific growth drivers from International Diagnostics and Surgical. These drivers are sometimes overlooked because of their strong market shares in the U.S., however we still have a great growth opportunity outside of the United States. That said, internationally – molecular STI testing, cytology and MyoSure – all delivered nice growth in the quarter. This underscores the power of the sum of our parts, and reinforces our opportunity and ability to grow by expanding markets.

Let's start with STI testing – the largest category in our global molecular diagnostics business. In the U.S., STI testing is our largest category and we have earned and maintained leadership for years. Internationally, we are still in the early days of leveraging our expanded Panther installed base. We have a sizeable opportunity to increase our share, not only in STI testing but across all categories where we offer testing.

We have a long runway ahead of us as we continue to build the new markets we've entered. With several irons in the fire we expect to layer in more contribution over time, driven by more assays and more volume on our Panther systems.

The same can be said for cytology and cervical cancer screening. In some regions of the world, we are bringing liquid-based pap tests to the market for the first time and subsequently growing the market. While overshadowed by the U.S. revenue, international cytology, like STI testing, adds meaningful revenue that moves the needle over time.

Shifting to Surgical and MyoSure – while MyoSure is still growing strong in the U.S. – the MyoSure international growth rate is even higher. This is possible because international markets are vastly underpenetrated, and demand remains high for our minimally invasive option for treating uterine polyps and fibroids. In many regions, we are the first and only minimally invasive alternative to a complete hysterectomy. And it's our belief that all women should have access to minimally invasive options.

All in, while its clear that certain products across our portfolio are more established in the U.S., what is not as obvious is that there are meaningful market expansion opportunities for these same products internationally. As leaders in these areas and champions for women's health, we are well positioned to capitalize on this global growth opportunity.

And finally, before turning the call over to Karleen, I'd like to provide more detail on Endomagnetics. As Steve mentioned, we are pleased to welcome the Endomag team to Hologic. 150 employees strong, and with seasoned management and R&D capabilities, the company has done an incredible job growing the business to what it has become today. That includes 500,000-plus women treated and adoption by over 1,300 hospitals in over 45 countries.

Endomag products include Magseed markers for wireless lesion localization, Magtrace for lymphatic tracing, and Sentimag, a simple, easy-to-use handheld device to visualize both. The Endomag portfolio enables us to provide robust and differentiated offerings to meet demand in the growing interventional breast surgery market.

From an investment perspective, the business directly aligns with our Breast Health franchise and has proven on-market products that are well accepted into clinical workflows. With our established, deep-rooted sales channels we expect to amplify revenue growth well above our corporate average and also expect both margin and earnings accretion over time.

Overall, we are excited to join forces and determined to go even further together.

Now, I'll turn the call over to Karleen.

Karleen Oberton
CFO

Thank you Essex, and good afternoon everyone.

In my statements today I will provide an overview of our revenue results, walk down our Income Statement showcasing strong performance, touch on certain key financial metrics, and finish with our guidance for the fourth quarter and full fiscal 2024.

Our third quarter financial results were robust, once again exceeding our expectations on revenue and profitability, building on the momentum from the first half of the year. To recap high level results, total revenue came in at $1.011 billion, beating the midpoint of our prior guidance by $11 million. We delivered 3.1% revenue growth and organic growth of 5.8%, excluding COVID. In addition, Non-GAAP earnings per share were $1.06, growing 14.0% and exceeding the high end of our prior guidance by 1 cent.

Before moving on to our franchise results, we want to highlight the continued strength of our balance sheet. In Q3, we generated over $400 million in cash from operating activities -- ending the quarter with $2.4 billion on the balance sheet, deployed $100 million on share repurchases, and announced the acquisition of Endomagnetics.

We continue to demonstrate that our strong cash balance, leverage ratio well below our target range, and ability to generate cash consistently provide us the flexibility to fund innovation and pull both levers of our capital allocation strategy, tuck-in M&A and share repurchases, at the same time. Moving forward, we still have significant firepower to continue to deploy capital diligently, as opportunities arise.

Turning to our franchise results, in Diagnostics, third quarter revenue of $440.8 million grew 0.7%. Excluding COVID assay and related revenue, worldwide Diagnostics grew by 6.0%.

Within Diagnostics, Molecular Diagnostics continues to contribute significantly, growing 10.5% excluding COVID. We continue to see underlying strength in BV CV/TV, which continues its outstanding growth trajectory and has become our second-largest assay globally.

Additionally, as expected, non-COVID respiratory assay sales declined sequentially from Q2, in line with the flu season. However, year-over-year growth remains strong, highlighting the continued adoption of our 4-plex COVID, Flu A, Flu B, and RSV assay. Finally, Biotheranostics continues to be accretive to growth for our Molecular business.

Rounding out Diagnostics, Cytology and Perinatal declined 2.9% globally, with US declines partially offset by solid international growth, as Essex highlighted earlier.

As a reminder, in fiscal Q3'23, customers built up cytology inventory levels in the U.S. due to third-party shipping constraints in Q2'23, leading to elevated sales in the prior year period. While the cytology business has largely returned to normal, year-over-year growth rates were impacted. Looking ahead, we expect flat to modest growth from the cytology business.

Moving on to Breast Health. Total third quarter revenue of $385.0 million increased by 7.1%, or 8.2%, when excluding SSI.

Within Breast Health, growth was primarily driven by Breast Imaging, with solid domestic and international results – contributing 7.2% and 12.1% growth, respectively, excluding SSI. Third quarter performance was driven largely by increased gantry shipments and robust Service revenue growth that continues to contribute meaningfully.

Continuing next to Surgical. Third quarter revenue of $166.6 million increased 6.2%. Surgical growth continues to be fueled by MyoSure and the related Fluent Fluid Management System. Our Laparoscopy business, while smaller in dollars, grew significantly in the quarter and continues to progress nicely. Additionally, International continues to be a bright spot, growing just under 20% in the quarter.

Finally, in our Skeletal business, third-quarter revenue of $19.0 million declined 29.7% due to lower Horizon DXA shipments resulting from a temporary stop-ship related to a non-conformance issue. We are working with our suppliers to resolve this situation and expect to resume shipments during the first quarter of fiscal 2025.

Now, let's move on to the rest of the non-GAAP P&L for the third quarter.

Gross margin was 61.1% for the quarter, a 30 basis point improvement from the prior year period, even though COVID assay revenue declines continue to be a headwind. Additionally, gross margin expanded 40 basis points sequentially from fiscal Q2 primarily driven by favorable product mix.

Total operating expense of $302.8 million in the third quarter decreased by 3.5%. This decrease was driven primarily by elimination of expenses related to the divested SSI business.

Operating margin was 31.2% for the third quarter. The year-over-year increase of 230 basis points was driven by top-line growth, expanding gross margins, and lower operating expenses. Sequentially, as expected, operating margins expanded 80 basis points from Q2, largely from lower operating expenses and higher gross margin in Q3.

Below operating income, other income, net, represented an expense of nearly $3 million in our fiscal third quarter. Interest income is lower due to lower cash balances from the significant share repurchases we have completed throughout the fiscal year. Additionally, interest expense is up due to higher interest rates.

Finally, our tax rate in Q3 was 19.75% as expected.

Now let's move on to our Non-GAAP financial guidance for the fourth quarter and full year fiscal 2024.

For Q4 2024, we are expecting total revenue in the range of $970 to $985 million and EPS of $0.97 to $1.04. For the full year 2024, our guidance assumes revenue of $4.012 to $4.027 billion and EPS of $4.04 to $4.11.

Unpacking this guidance, we lowered the midpoint of our prior revenue guidance by $5 million, which represents about a $20 million headwind related to the temporary Skeletal Health stop-ship previously mentioned, partially offset by our strong performance in Q3 and the inclusion of an estimated $4 to $5 million of revenue from Endomagnetics – now that we have closed the acquisition.

With respect to foreign exchange, we are assuming Q4 will have a headwind of about $3 million. For the full year, we now expect a slight tailwind of about $3 million.

Turning to our franchises, we expect Diagnostics, Breast Health, and Surgical to grow mid-single digits in Q4 and full year fiscal 2024, excluding the impact of COVID. As a reminder, fiscal '24 has four fewer selling days compared to fiscal '23, which we estimate to be a headwind of more than 100 basis points for the full year.

Starting with Diagnostics, in Q4 we expect our Molecular Diagnostics business to drive high single-digit growth, excluding COVID, as customers continue to adopt and drive utilization of our broad Panther menu.
In Cytology and Perinatal, we expect growth in the mid-single digits for the fourth quarter. Sequentially, however, we expect the business to perform flat to Q3. In Q4 of last year, sales

dropped below typical ordering patterns due to inventory buildup in Q3'23. We expect Cytology and Perinatal comps to stabilize in fiscal year '25.

Closing out on non-COVID Diagnostics, we expect Blood revenue of approximately $6 million in Q4 and $29 million for the year.

In terms of COVID revenue, we expect COVID assay sales to be about $7 million in Q4 '24, and about $70 million for the full year. COVID-related items are expected to be about $25 million in the fourth quarter and approximately $105 million for the full year.

Moving on to Breast Health. We remain on pace to grow the business mid-single digits for the fourth quarter. We expect to see solid gantry placements in Q4, continuing the steady performance we have delivered year-to-date. The demand for our portfolio of products and services remains strong, and we have solid visibility into gantry orders.

Further, our confidence in delivering more gantries than last year remains high. We are successfully managing resource availability among both our install teams and our customers, as customers balance the need to meet elevated demand for screening and staffing constraints.

Finally, in Surgical, we anticipate Q4 revenue to grow mid-single digits. We expect the growth to continue to come from MyoSure, Fluent, and laparoscopy.

Moving next to margins, our guidance continues to assume a cadence of improvement moving into Q4, for both gross margin and operating margin. We remain on pace to exit the fiscal year in the low 60s for gross margin. Our guidance also assumes Q4 operating margins in the low 30s, and we are on pace to finish fiscal '24 between 30 to 31% -- which includes the stub period phase-in of Endomagnetics.

Below operating income, we estimate fiscal '24 other income, net, to be an expense of approximately $8 million in Q4 and $11 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 238 million for the full year.

To conclude, Q3 was another strong quarter for Hologic. We continue to deliver robust growth and quality earnings. As we approach the end of fiscal year 2024 and look ahead to 2025, we are excited by the performance across all our franchises and the additional strength provided by a pristine balance sheet. As always, our stakeholders can count on us to deliver while also advancing the state of women's health around the world.

With that, we ask the operator to open the call for questions.