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Hologic, Inc. (HOLX)

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MANAGEMENT DISCUSSION SECTION

Andrew Cooper
Analyst, Raymond James Financial, Inc.

Good morning, everyone. Thanks for joining us at the Raymond James Institutional Investor Conference. I'm Andrew Cooper. I cover diagnostics and tools here for Raymond James. Excited to have Hologic joining us this morning. Company is a leader in the women's health space across several end product areas that we'll get into in our conversation. But pleased to have CFO, Karleen Oberton, with us for a brief presentation and then a little bit of kind of fireside chat Q&A, as well as Mike Watts, in IR, up on stage with me as well.

So with that, I'll pass it to you, and we'll get into the conversation after that.

Karleen Marie Oberton
Chief Financial Officer, Hologic, Inc.

Great. Thank you, Andrew, and good morning, everyone. It's a pleasure to be here. Hologic, a medical technology company uniquely focused in women's healthcare, a company where our 7,000 employees globally are galvanized by a purpose, passion, promise in regards to women's healthcare. Our purpose is to enable healthier lives everywhere, every day. Our passion is to be champions of global women's health. And our promise is The Science of Sure. And it's The Science of Sure that leads to clinically differentiated market-leading products in each of our divisions.

So, safe harbor statement and non-GAAP measures. So, at a high level, we're organized into three divisions, breast and skeletal health, diagnostics and surgical. We have many different revenue platforms. The majority of our platforms are recurring in nature, over 80% in FY 2024, the largest of which is disposables, which is basically our diagnostics and surgical businesses; followed by service, which is largely related to our breast health business; and our capital business, less than 20% in 2024 related to our breast health business.

From a geography perspective, we are 75% US and 25% OUS, clearly under-indexed from other medical technology companies. But again, given we are uniquely focused in women's health, there are challenges – kind of structural challenges outside the US, but that is really one of our growth opportunities. And over the past 10 years, we have differentiated investment toward international expansion, commercial capabilities. And we've

seen, year after year, over 10% growth internationally because of those investments and believe there's still opportunity outside the US to grow.

So, we'll get into each of our divisions. Diagnostics is our largest division, which has grown over 6% over the past 10 years. That growth has been led by our molecular diagnostics portion of that business, and in particular, the explosion of Panther placements during COVID. So prior to COVID we had about 1,700 Panthers worldwide. We have over 3,300 worldwide now. And those Panthers are sticky. Nothing's being returned because COVID's over, I think. We're continuing to drive utilization in all those Panthers and we've seen that in Q1, the quarter we just closed, close to 11% growth in our molecular business.

So, we have all these Panthers placed. We're driving utilization with a differentiated menu. We have over 20 assays approved on the Panther in Panther Fusion platform. We believe it's still plenty of run room for growth for our molecular business that we've seen nice growth over the past couple of years, driven by our newer assays, BV/CV in particular, as well as acquired technologies in Biotheranostics continues to drive accelerated growth.

Part of the diagnostics business is our cytology business, which you can see from 2014 is roughly flat to down slightly as we see a flattish, down slightly market in the US with some growth outside the US. We continue to invest in cytology despite being a flat business with the recent launch about a year ago of our Genius digital cytology, where we believe that will be a platform to secure that business and potentially drive some growth in the future. Think about one of the rate-limiting challenges for cytology outside the US is lack of cytologists. With digital cytology, you can take a sample, digitize it and send it to wherever the cytologists might be anywhere in the world to read that image. Again, expanding women's health around the globe.

Our breast health business is a business led by our 3D Genius mammography machine, market-leading mammogram machine, close to 80% share in the US, so really own the space with a clinically differentiated product. We continue to invest in this business both organically and inorganically and expand beyond screening in the gantry, expanding into interventional and breast surgery. We've just announced probably a couple of months ago the acquisition of Endomag, which expands our breast surgery capabilities. Really excited about adding that asset and the R&D portfolio pipeline that it has to the breast business.

Organically, we continue to invest. We have a next generation gantry, Envision, which we expect to launch sometime in 2026, which will bring improved patient experience, better access, better workflow and, of course, superior imaging with that next generation gantry.

The largest piece of that business is actually a service business, which is tied to the installed base of gantries around the world. Typically, customers sign up for three- to five-year long-term contracts. So, it's revenue that's recurring in nature and predictable. We've also, the past couple of years, really intentionally focused on our processes, capabilities and leadership in the service business. And that continues to drive margin improvement in this mature business. Really excited about what we've done there. And those investments will continue and they will – we invest across what we call the patient continuum of care from screening, diagnosis and treatment.

And finally, our surgical division, which has grown 7.6% over the last 10 years, really led by our MyoSure and Fluent platform for the treatment of fibroids. We continue to invest both organically and inorganically as well for this business. Inorganically, we announced the acquisition of Gynesonics at the beginning of January, which complements our platform, our offerings to treat fibroids. So think about fibroids as a leading cause of abnormal uterine bleeding that have different sizes and different ways to be treated. So, our smaller, zero to two are treated by our MyoSure, two to five are treated by Gynesonics in the Sonata platform that we recently acquired. And then

larger fibroids and those maybe outside the uterus and treated by our Acesa platform and laparoscopic capabilities there.

Surgical, we continue to invest organically, specifically in our international business. We've seen 20% plus growth for several years in that business, as we attain reimbursement, promote guidelines for our portfolio of product offerings there, and believe that international continue to be a platform for growth for the surgical business.

Put it all together, over the last 10 years, 4.8% growth on the top line and over 10% growth in the bottom line. And while the slide shows a nice straight arrow up and to the right, it certainly didn't happen that way. There was peaks and valleys along the way with the peak in 2021 with over \$2 billion in COVID revenue and challenges in other parts of our business. In this moment, we have some challenges with our breast business for a couple of quarters, but we're confident that we will overcome those and we'll see this trajectory of growth over time. Again, nothing's as straight and up and to the right, but we're ready to manage and deliver overall over the long term.

So, in summary, solid revenue and EPS growth. Again, we have clinically differentiated market-leading products, which really create a moat for our products and our commercial teams, and it allows us to add growth platforms, again, both organic and inorganic, to those large installed base. Think about, as I mentioned, Panther, over 3,300 installed globally; 3D mammography, well over 11,000 just in the US alone. Incredible installed base, incredible assets to build from.

We continue to deploy cash inorganically, acquiring early stage companies, recently Endomagnetics and Gynesonics. We have exceptional operating margins in the low-30s to drive really this exceptional cash flow. On average, we'll deliver close to \$1 billion of cash flow every year. We have a pristine balance sheet, a best-in-class credit facility. So, our focus is how do we continue to deploy that cash flow between acquisitions and share repurchase to deliver top and bottom line growth.

Thank you.

QUESTION AND ANSWER SECTION

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Great. If you want to come, join us over here and take a seat, make yourself comfortable. But I think that overview was super helpful. I'm going to ask a little bit different of a first question than I often do in these. You've been at Hologic since I think 2006. So...

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

I started very young.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

That's right. So, a lot of change. I think revenues are close to 10x what they were in 2006. What are you sort of most proud of that Hologic has accomplished over that time and what keeps you excited to be at Hologic now and into the future?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Thanks, Andrew. It's a great question. I think, most importantly, it's what we do for women's health, right. No one's out there doing what we do to address guidelines, to address coverage, to bring the healthcare to women that they need. You think about breast cancer screening with our 3D mammography and the rates of cancer death that have come down dramatically over the last 10 years, that's because of that screening platform. Think about cervical cancer screening in our ThinPrep PAP tests, again, that used to be one of the leading killers of women, and it's now we've almost eradicated it. But except for interval expansion, we're seeing rates come back again. But essentially, we did that with our products.

And we continue to do it even with things like STD screening out of our molecular business. I [ph] don't (00:11:05) think people realize that most of that screening is done as part of a woman's well visit. She's asymptomatic. The doctor asks her a couple of questions based on her sex activity and screens her for STDs. And that early intervention and the potential treatment for an undetected STDs prevents things like cancer down the road, prevents things like infertility. So, those are the things that we do to really drive women's health every day.

And then, I'd say one thing specifically is really proud of what we did during COVID, right. I think we've responded to one of the biggest crisis that we've ever seen in our lifetime with testing. And I would say that Steve and I had a great partnership through that in that we didn't get over our skis on head count. We had tremendous revenue and tremendous cash that it was easy to just spend and hire people. But we were constrained. We knew it would eventually come down. Came down pretty quickly. But over that time, during that peak of – over 2 billion and less than 35 million in this year, we didn't lay off any people because of COVID. Right? So, I think we responded to the world's need, but also took care of our employees at the same time.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

And like you said, hopefully something that we put in our past now at this point...

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Right.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

...just for the sake of society. Okay. Well, diving in a little bit to, let's say, where there was maybe a little bit more noise on the fiscal first quarter and this year. When did you kind of start to see a little bit of a different scenario in breast health playing out than what you initially expected? And what was it that kind of flagged that and why weren't we able to see it a little bit sooner in the process?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. So, I would say, let's frame that 2022 and most of 2023, we were on chip allocation, right? And so, there was this pent-up demand for gantries. And that pent-up demand early on in 2023 and early 2024 continued to play out. And I think we maybe mistook that pent-up demand for actual underlying demand, right? And so as we get into 2025, the pent-up demand is behind us, but we're also in a different market than we were kind of prior to COVID. Prior to COVID, we were in a 2D to 3D market, where people were still converting, where there was higher reimbursement, superior technology that drives that conversion. Now, we're in a 3D to 3D market, specifically in the US, where that is a different decision for a hospital or a breast center. It's a longer decision. Things like interest rates play into that decision as well.

So, found ourselves in a little bit of a different market, I think, coupled with probably we could have done a little better on the execution and refocused capabilities in our team, and that's part of what's going on here Q1, Q2, and why we expect some improvement in the back half of 2025. I would also say internationally, the market's a little different where we see, specifically in Europe, in the UK, different economic challenges as you see health systems try to prioritize their spending. There's new administrations, both in the US, as we know, and outside the US that are playing into decision-making and probably a longer – holding on to those gantries a little longer. And fortunately, we have great service teams that allow our customers to do that.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

And that last piece is something I wanted to touch on a little bit. So, maybe just remind us, what that typical sort of gantry replacement cycle looks like and how folks are, or the degree to which they may be sort of trying to extend that. And is that related to the Envision rollout next year in terms of the latest gantry update?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. It's going to vary by customer and volume. But typically, would have said the average life is 7 to 9 years, 10 is on the upward. And even as I talked about Europe, they used to be some countries would have statutory requirements that at year 10 it had to be updated. Those have kind of been waived. And now, we're seeing a 10- to 12-year average life in some cases. So, it has expanded. And again, it's a great product. We proved through the chip allocation process that people actually could hang on to them longer. And again, we have superior service teams that support our customers the best they can.

Andrew Cooper*Analyst, Raymond James Financial, Inc.*

Q

Okay. Helpful. And you highlighted the services business there in the breast health side of the business overall, grown really well. I guess, maybe my question is, how does that interact with that gantry trajectory, right? Presumably, there's some warranties on the front end, older machines need a little bit more service. How do we think about the pace of that service growth given what's going on in the gantry business?

Karleen Marie Oberton*Chief Financial Officer, Hologic, Inc.*

A

Yeah. So, we have pretty high attach rate on the gantry business. Meaning, I think well over 75% of our customers have a long-term service contract in place. So, it's not much less time and material. So, everything's covered under the contract. And so, I think what we're seeing, and we saw this in Q1, we had a really nice growth rate in service, I think it was over 8%, is as people hang on to the gantries, we're having a little uptick in the service now. As gantries come back, you're right, the first year is typically under warranty, so we'll kind of see maybe a little more stabilization on that service as people drop into warranty for a year and then come back under the service contract to you later.

Andrew Cooper*Analyst, Raymond James Financial, Inc.*

Q

Okay, helpful. Maybe moving a little bit to the interventional side of the breast health business. 1Q, I don't think we spent as much time talking about it on the earnings call or immediately after, but that business was a little bit light as well. I think it was down a touch organically in the quarter. How should we think about the headwinds that were in that side of the house and what that bounce-back could or should look like?

Karleen Marie Oberton*Chief Financial Officer, Hologic, Inc.*

A

Yes. I think there are a couple of dynamics at play. I think I talked about this sales organization that we are kind of refining that organization to have a distinct kind of surgery versus capital because, again, different capabilities to sell big iron versus the procedure-type stuff. So, that wasn't in place in the quarter. I think a tough comp. I think the Q1 2024 was close to a 10% growth quarter. We've had some product recalls with the [ph] BioZorb (00:17:23), which played into that. And I think we had a couple other kind of stop-ships, smaller items that played into that quarter's performance.

But more importantly, Andrew, just so excited to add Endomag to that franchise. As I mentioned, it's not just a couple of products where we acquired kind of some leadership capabilities, R&D capabilities in a portfolio that we're excited to bring to the market.

Andrew Cooper*Analyst, Raymond James Financial, Inc.*

Q

Great. And in the interest of time, I want to move to molecular diagnostics. Like you highlighted, kind of the biggest piece of the pie at this point. And it's grown really well, despite the fact that you did so many Panther installs in a short period, how should we think about the runway there with the existing instrument base, knowing that, yeah, you're still probably working through that bolus where we're not going to see the same level of placements that we saw over the last five years?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. I'd frame it differently and say that we have – continue to grow because of that installed base, right? So, what we're doing now is we don't have to place another Panther, it's drive utilization on the Panther. So, we've got the best-in-class, high-throughput, automated instrument with a menu of over 20 assays approved with the Panther and the Fusion sidecar. And so once a customer has that Panther, the lab techs love it, right, because it has the most walk-away time for the lab tech, right? And once they're installed, they see the value. Then it's like we add the menu to it, right? And that – what's continues to drive that utilization and drives the growth rate. And again, we'll probably have, for the next couple of years, lower Panther placements, but that's okay. We have plenty of room to drive the utilization on the installed base we have.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Certainly still above trend from where we kind of thought we would be pre-pandemic.

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

But maybe on the Fusion sidecar side of that, what do those conversations look like to drive that attachment? And then when you think about new menu, I think at some point, there's been some comments of, hey, a lot of it might be on Fusion. So, how do we think about that as a driver?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah, I think it's a customer by customer, depending on what is the menu that they're running right now. The majority of the Panther Fusion is respiratory. So if that's what the lab is running, that's what we're focused on discussing with them. The future of maybe GI and hospital-acquired infections also would be on the Fusion sidecar. So, really depends on what the customer is running in the lab and what they see as the assays they want to be running in-house.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

And thinking about specific assays that have been big drivers, BV/CV/TV has been a great new menu addition over the last – not brand-new at this point, but really a great growth driver. How do you think about that next big assay and where the gaps in the menu – probably not the fair word, but where the opportunities in the menu lie to continue to add?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. I would say there's still run rate on BV/CV. I would say, sports analogy, mid-innings, is that a term? Think about BV/CV approved in 2019, probably the takeoff delayed because of COVID, really have been focused on our larger lab customers. We are just turning on our physician sales force. So, that's kind of what I'll call our secret sauce in our diagnostics business, that the physician sales force partners with the lab to get customer-level data

and goes out to educate physicians on guidelines and how they should be screening. So, we're just turning on that team to BV/CV. So, that's what gives me confidence that there's still run room there.

Still early days on Biotheranostics and acquisition we did in the CLIA Lab capabilities that we now have. That's over \$100 million now and think again that growth rate will be accretive to that franchise average. And then there's more, again, GI, hospital-acquired infections and other things that are coming down the road. Nothing the size of BV/CV. I think it's pretty unique. But feel like we've got room to run with what we have right now.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Okay. And maybe just touching on one more that was kind of a topic in the first quarter, you stripped out around \$30 million of PEPFAR revenue with the kind of stoppage of funds, at least temporarily. You've got the waivers in place. How do we think about the potential for that revenue to come back? And what needs to happen to see that play out?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. Unfortunately, despite some waivers, they actually haven't made it through in the supply chain, and the party that we contract with is still under a stop work and hasn't been paid. So at this point, given this – what we're hearing is significant disruption on the ground, I really don't see that coming back in any meaningful way for the balance of the year, unfortunately.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Okay. Fair enough. Shifting to surgical, you called out MyoSure and Fluent. I guess, those have been great growth drivers for a while now. How do we think about the runway of opportunity there? And I think, importantly, as well from an M&A perspective, are there things in that side of the house that are especially attractive today?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. So, I think we've done a great job with MyoSure and Fluent, right, and we just launched Fluent Pro next generation Fluent with some improvements that have been really well-received and doing really well since launching at the beginning of the year. I think about those products in particular as well as NovaSure have tremendous room to grow outside the US. Again, been intentionally investing in market access, development capabilities, to get guidelines, to get reimbursement, and believe we'll still see growth there. And then with Gynesonics, that acquisition in the Sonata platform, kind of again building out that fibroid portfolio, if you will, we believe that's not only good to add Gynesonics, but [ph] it's likely will (00:23:19) create some pull-through in the rest of the portfolio.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

In nearer term – there's been some disruption on the IV solution shortages early in the year. I guess, what's the opportunity to recapture some of those patients that were kind of pushed out because this is a procedure that uses a lot of fluid, frankly?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. Unfortunately, I don't know if there's a big recapture to happen. Think about Q1 – calendar Q4 is our biggest surgical quarter. Because it's an elective procedure, people are kind of having it done because their deductibles are behind them. So if you didn't get the procedure done, your deductibles reset, you might continue to defer to have that procedure until later in the year.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Okay. Maybe stepping back, thinking about kind of the high level, a few months ago you shifted the tone a little bit to mid-single digit organic growth on the top line for a long-term algorithm, you were at 5% to 7% for a three-year window, but I think a lot of people sort of perceived it as if it was long term. You're sticking with double-digit earnings growth. So, maybe this is a long-winded intro into the capital allocation question and how that's evolved to close that gap when you've also talked about leading operating margins that maybe don't expand as much from 2025 to 2027 as they did in the couple years prior.

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. So I think we've talked – as you said, the mid-single digit growth on the top line and double-digit growth on the bottom line, that does require some margin expansion, but I think there are growth drivers on the top line, international is diluted to the corporate average. Some of the acquisitions come in a little lower, but we're always looking at the base and trying to leverage the base to fund those activities that drive the top line.

But again, I think from a capital allocation perspective, tremendous cash flow, great balance sheet, great credit facility. How do we deploy it? The priority is going to be M&A because that drives the top line. And then we'll look at share repurchase as needed when there's opportunities in the market, one, at a minimum to manage solution, but then to close that gap if we need it on the double-digit earnings.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Yeah. And that is one thing I wanted to touch on. You did pick up the pace of some of the repurchases, kind of, of late. Is it the simple math and kind of what's available out there from an M&A perspective that really dictates how you think about share repurchase in any given period? Or just help us think about how much of that capital allocation we should think about being repos over the longer term?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. So, I think what we've said is, at a minimum, we're going to manage dilution. So, that's about 3 million shares a year from our equity plans. I think what we've seen is, I think, it's been disciplined in the M&A front, right? So, we've had the two acquisitions of late. We had a couple of years with no acquisitions, where we had the opportunity to do a little more on the repurchase. So, I think we prefer to do the M&A than the repurchase, but the great news is we can do, Andrew, right?

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Absolutely. And then, maybe just an update on something I feel like we talked about when it was first announced and not as much since, but you did do a JV kind of stepping a little bit outside of the women's health focus. Can you give an update on [ph] Maverix (00:26:51), the efforts in lung cancer, and maybe how you think about leveraging some of the core competencies and capabilities you have beyond that traditional focus?

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. So, let's think about – as we think about women's health, right, I think right now, today, we are focused in women-specific organs, right? But if we think about women's health with a broader lens, there are diseases that affect both men and women, but have different outcomes or predominance in women, and lung cancer is one of those. Globally, lung cancer is the leading killer of women. So, I think the one that gives us a right to play within women's health, and then to your point on leveraging core competencies, there's a lot of similarities in the breast business, right? So, there's a screening element, a biopsy element, a diagnosis element, and a treat element. And we think we have the competencies, if the right assets are put together, to drive that type of business.

So, I think it's a unique opportunity to kind of have a strategic investment that doesn't – we don't fully absorb all the losses at this point in time, allows us to learn more about that space, learn how they kind of build that business, and then decide whether it's right for us or not.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Q

Great. And maybe just in the last minute or so, I'll pass it back to you and what you want to leave folks with or what you think is least appreciated in the market today about the Hologic story.

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

A

Yeah. I think – well, one, I think we're at tremendous value right now. I think there's outsized focus on one piece of the business that's having a challenge. But as I articulated, we see line of sight to getting over that challenge. And we see a strong future. And again, we're a company that we're facing this challenge from a position of tremendous strength. Most companies don't face challenges from a position strength and that gives me confidence that we'll be able to address and it and continue to grow the business.

Andrew Cooper

Analyst, Raymond James Financial, Inc.

Great. We'll stop there. we'll head down [ph] Amaranti 1 (00:28:41) for the breakout session. Thank you so much.

Karleen Marie Oberton

Chief Financial Officer, Hologic, Inc.

Great. Thanks.

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