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Hologic, Inc. (HOLX) CEO Steve MacMillan on Q4 2019 Results - Earnings Call Transcript

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FQ4: 11-06-19 Earnings Summary

Press Release SEC *10-K*

EPS of $0.65 | Revenue of $865.8M (6.43% Y/Y) beats by $19.31M

Earning Call Audio

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Hologic, Inc. (NASDAQ:HOLX) Q4 2019 Results Conference Call November 6, 2019 4:30 PM ET

Company Participants

Mike Watts - Vice President of Investor Relations and Corporate Communications

Steve MacMillan - Chairman, President and Chief Executive Officer

Karleen Oberton - Chief Financial Officer

Conference Call Participants

Tycho Peterson - JPMorgan

Bill Quirk - Piper Jaffray

Jack Meehan - Barclays

Ivy Ma - Bank of America Merrill Lynch

Chris Lin - Cowen

Mason Austen - Morgan Stanley

Anthony Petrone - Jefferies

Andrew Brackmann - William Blair

Dan Brennan - UBS

Operator

Good afternoon. And welcome to the Hologic's Fourth Quarter Fiscal 2019 Earnings Conference Call. My name is Cody, and I am your operator for today's call. Today's conference call is being recorded. All lines have been placed on mute.

I would now like to introduce Mike Watts, Vice President of Investor Relations and Corporate Communications to begin the call.

Mike Watts

Thank you, Cody. Good afternoon. And thanks for joining us for Hologic's fourth quarter fiscal 2019 earnings call. With me today are Steve MacMillan, the company's Chairman, President and Chief Executive Officer and Karleen Oberton, our Chief Financial Officer. Steve and Karleen both have some prepared remarks today, and then we'll have a question-and-answer session.

Our fourth quarter press release is available now on the Investors section of our Web site. We also will post our prepared remarks to our Web site shortly after we deliver them. Finally, a replay of this call will be archived through November 29th.

Before we begin, I'd like to inform you that certain statements we make during this call 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 that's included in our earnings release and in our filings with the SEC.

Also during this call, we will be discussing certain non-GAAP financial measures. A reconciliation to GAAP can be found in our earnings release. Finally, any percentage changes we discuss will be on a year-over-year basis and revenue growth rates will be expressed in constant currency unless otherwise noted.

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

Steve MacMillan

Thank you, Mike. And good afternoon, everyone. We're pleased to discuss Hologic's financial results for the fourth quarter of fiscal 2019, our sixth consecutive quarter of good consistent results.

Total revenue came in very strong at $865.8 million, a 7.3% growth rate in constant currency that exceeded our guidance. Improving operating and net margins drove non-GAAP earnings per share of $0.65, an increase of 12.1% and in-line with our expectations.

We wrapped up fiscal 2019 with our best revenue growth of the year. This growth was balanced, with sales increasing in each of our divisions, both domestically and outside the United States. In addition to very good results in our largest businesses, Breast Health and Molecular Diagnostics, we were excited by the continued strengthening of Surgical, which posted its best growth in 10 quarters.

Before we discuss the quarterly details, let me step back and give a status report on the company as a whole since we're marking the end of our fiscal year. We have clearly made a lot of progress over the last six quarters. In the first half of fiscal 2018, our overall growth rate was about 2%, if you strip out the divested Blood Screening business and the inorganic benefits of Cynosure.

We restructured our leadership team around that time. And by the second half of last year, growth had improved to the 4% range. And for the full year of fiscal 2019, growth was 5.7%, well ahead of our initial guidance as we added two tuck-in acquisitions to solid underlying organic growth of about 4%. This organic performance, which excludes currency movements, blood screening and Faxitron and Focal, is impressive when you consider that we operate in several flat or declining markets, where our leading market shares make it challenging to grow. In short, we had executed well over the last year and a half and expect to do the same in fiscal 2020.

Now, let me break down our performance further by providing a brief snapshot of how we're doing each of our major franchises. In U.S. Breast Health, which grew 9.1% for all of 2019, we are using internal R&D and external acquisitions to build on an incredibly strong domestic leadership position in 3D Mammography. By leveraging our install base, we are creating a steadier, more diversified growth engine across the continuum of breast healthcare.

In domestic diagnostics, which grew 4.5% for the full year, we are partnering with our customers to drive market growth and leveraging our install base of fully automated Panther instruments, with the broadest assay menu in the mid to high volume molecular space. In U.S. surgical, which grew 2.8% for the fiscal year, we have revitalized our sales force and our R&D engine to drive steadily improving growth.

In domestic medical aesthetics, which declined 9.9% for all of 2019, we have stabilized our U.S. sales force as we await internally developed and externally licensed new products to drive growth. Outside the United States, where revenue grew 8.2% in 2019, we have transformed what was effectively a startup a few short years ago into a consistent growth driver, with much opportunity ahead for both revenue growth and profit improvement.

With that introduction, let's discuss our fourth quarter results in more detail. Revenue of $865.8 million exceeded our guidance and grew robust 7.3%. Within this, the acquired Faxitron and Focal businesses contributed $14.6 million to revenue. We were off to a good start with these deals with low-teens growth for the full year on a pro forma basis.

Excluding sales from our divested Blood Screening business, which increase in the fourth quarter revenue of $849.1 million grew 6.9% still our best overall growth rate of the year. In terms of geography, domestic sales of $656.2 million increase a very healthy 6.7% in the quarter. Excluding Blood Screening again, U.S. growth was 6.2%, accelerating for the fifth consecutive quarter. Outside the United States, sales of $209.6 million increased 9.2% in constant currency, a nice rebound compared to the third quarter.

Now, let me provide some more detail on our divisional revenue results. In our biggest division, Breast Health, our core 3D Mammography business remains rock solid and we are building on it with an increasingly diversified product portfolio that spans the continuum of breast healthcare. Based on internal R&D productivity and strategic acquisitions, we have established ourselves as the trusted experts in Breast Health. We offer innovative products that deliver better clinical outcomes for patients and workflows that make life easier for customers. Together, these translated to steadier, more predictable revenue.

In the fourth quarter, underlying trends in Breast Health remained strong. Global sales totaled $342.6 million, an increase of 7.1% against the tough prior year comparable. In terms of geography, domestic Breast Health revenue grew a healthy 6.4%. Outside the United States, we were pleased to post sales growth of 9.4%, accelerating compared to the third quarter. In terms of breast sub segments, imaging sales grew 6.5% while interventional sales increased 10.2%, as we focused on selling our growing portfolio. Imaging benefited from about $10.4 million of Faxitron sales while Interventional included $4.2 million of Focal revenue.

In Imaging, sales of our Genius 3D systems increased strongly, establishing a new quarterly record some eight years after the domestic launch life, an impressive accomplishment by our commercial teams. On a cumulative basis, we have shipped about 6,900 3D systems in the United States, giving us a tremendous install base onto which we can layer additional revenue streams. We have converted more than 70% of our installed base to 3D. Yet, there are still more than 5,000 Hologic and competitive 2D systems in the United States, providing us multiple years of conversion runway at our current pace, especially as we continue to gain market share.

As in recent quarters, Imaging growth was driven by our new 3D performance and 3Dimensions gantries, demonstrating how innovative R&D is contributing to our growth strategy. Other new products, including Intelligent 2D, Clarity HD and SmartCurve, also added nicely to Imaging growth. We have a long-term opportunity to further enhance our existing 3D install base with upgrades like these, as well as the new artificial intelligence tools that we are developing and expect to launch this year. In Interventional, our fourth quarter results benefited from strong growth from biopsy disposables, which more than offset a headwind from lower Brevera capital sales due to the supply constraints we have previously discussed.

Before I turn to Diagnostics, let me update you on our pending acquisition of SuperSonic Imagine, or SSI, a French innovator in cart-based ultrasound technology. As a reminder, this tuck-in deal leverages our existing call points and is expected to be accretive to our revenue growth rate, albeit with some slight dilution to EPS in the near-term.

In early August, we acquired 46% of SSI's shares and have now opened a cash tender offer to purchase the rest of the company. Because we haven't finalized the acquisition yet, we recorded SSI's fourth quarter results under the equity method of accounting for investments. This means we booked no revenue or expense from SSI, but did record our share of their non-GAAP net loss, $1.8 million on a non-GAAP basis in other expense. We expect to close the deal by the end of our first fiscal quarter, and Karleen will tell you more about this.

Now let's turn to diagnostics, where revenue of $306.8 million increased 7.1% in the fourth quarter. Excluding sales from the divested Blood Screening business, diagnostics revenue grew 6.1%, still a very strong performance. Molecular remains the growth driver here, based on the productivity of our R&D team, which achieves 19 global clearances in fiscal 2019 and the sophistication of our lab and physician based sales teams.

In the fourth quarter, worldwide molecular sales of $172.1 million grew a very healthy 9.8%. Internationally, molecular grew 14.1%, well into the double-digit for the 13th time in last 14 quarters, against a very difficult prior year comp. And, in the U.S., although, we already enjoy higher market shares in key assay categories, molecular sales still grew 8.8%. This reflects how we work collaboratively with our customers to drive volumes and better patient care in established markets.

Molecular growth was again broad based in the quarter, as customers consolidated testing on our large install base of fully automated Panther instruments. Sales of our largest Aptima women's health assays, including chlamydia gonorrhea, HPV and trichomonas, increased at an impressive high single-digit rate overall.

Sales over many new products also added to growth, led by our quantitative viral load tests Panther Fusion and early contributions from our Aptima vaginosis assays. Panther has carved out a unique highly defensible leadership position in molecular diagnostics, just as our Genius 3D Mammography systems have in Breast Health. Over the course of 2019, our global install base of Panther's grew by more than 200, about the same amount as the year before. This brought our cumulative total to more than 1,700 units, 45% of which are outside the United States.

Importantly, utilization of these instruments has continued to grow as new assays emerge from our R&D pipeline, and as we partner with customers to drive overall testing volume. Average revenue for Panther is now about $240,000 a year on a global basis, and grew at a high single-digit rate in fiscal 2019.

Moving on, Cytology and Perinatal sales were $118 million in the fourth quarter, a small increase of 1%. Cytology sales increased slightly, all outside the United States, while Perinatal sales declined.

decline. Domestic growth in the cytology market remains challenged due to our high market shares and longer cervical cancer testing intervals. Elsewhere in Diagnostics, revenue related to our divested blood screening business was higher than expected at $16.7 million, an increase of 29.7% compared to last year. As a reminder, this revenue reflects low-margin products and services under transition agreements with Grifols. So the outperformance here hurt our gross margin percentage for the quarter.

Now let's turn to GYN Surgical, our most profitable division where growth has been consistently accelerating behind the re-energized sales force and a revitalized R&D pipeline. In the fourth quarter, sales of $114.5 million increased 7.3%, our fastest growth in 10 quarters.

We want to spend a little time highlighting the tremendous progress we've made in surgical, under the leadership of Sean Doherty, who's been named division President a little more than two years ago. Under Sean's leadership, U.S. revenue growth has increased sequentially in six of the last seven quarters against progressively more difficult comps. Underpinning this performance, we have made significant changes in the talent, structure and incentives of our domestic sales team. And these changes are paying off. At the same time, our surgical business outside the United States, while still small, has been growing rapidly and we've only scratched the surface of this opportunity.

From a product perspective MyoSure and NovaSure remain leaders in the fibroid removal and endometrial ablation categories, respectively. MyoSure remains a healthy grower with significant runway ahead as we launch line extensions and supporting products, and replace more antiquated methods. As for NovaSure, we believe our market share is stable, and in many cases, we are winning customers back, although, we need to slow category declines.

Finally, new products have begun to contribute materially to surgical growth. Most notably, our Fluent Fluid Management System and our Omni Hysteroscope, and we just launched our Omni Lok cervical seal and new Definity cervical dilator. So like Breast Health, Surgical is becoming much more diverse, enabling us to better leverage a large and strengthening sales force and we intend to add more new products in the future through both internal development and acquisitions.

Now let's turn to Medical Aesthetics where global sales of $76.9 million represented about 9% of consolidated revenue and increased 10.3%. As a reminder, we had an easy comparable in the prior year period as we booked a revenue reversal of $6.8 million associated with refunds and rebates of TempSure Vitalia in the fourth quarter of 2018. Excluding this, Cynosure sales would have been basically flat, reflecting a business environment that hasn't changed much. Specifically, our skin-related products continue to do well, while our lasers for body contouring in woman's health continue to struggle a bit as we await new products, both in-licensed and internally developed, to drive future growth.

To round out the revenue discussion briefly, skeletal sales of $25 million grew 3.7% based on growth of our DXA systems for bone density and body composition testing.

To wrap up, our fourth quarter results represent our sixth consecutive quarter of strong execution. Building on our market leading brands and large installed bases in the United States, especially in Breast Health and Diagnostics, we are expanding international internationally, churning out new products from our revitalized R&D pipelines and effectively integrating tuck-in acquisitions, while looking for more.

Now let me turn the call over to Karleen.

Karleen Oberton

Thank you, Steve, and good afternoon, everyone. In my remarks today, I'm going to walk through our income statement, touch on a few other key financial metrics, and then finished with our initial financial guidance for 2020. Unless otherwise noted, my remarks will focus on non-GAAP results, and percentage changes will be on a year-over-year basis in constant currency.

As Steve described, we are pleased with our fourth quarter results, as revenue $865.8 million exceeded our guidance and EPS of $0.65 finished in line with our expectations. Our performance was balanced and strong with sales growth in each of our businesses, both domestically and internationally. In addition, operating and net margins improved as we continue to manage the business for leveraged profitable growth.

With that introduction, let me start by reviewing our P&L for the fourth quarter. Gross margins of 61.7% decreased slightly by 10 basis points compared to the prior year period. This decrease was primarily due to higher manufacturing costs, the stronger U.S. dollar, trade tariffs in China and product sales mix. However, it's worth noting that gross margins did improve sequentially for the third straight quarter and we expect this trend to continue in 2020.

Total operating expenses of $279.3 million increased 5% in the fourth quarter. But excluding Faxitron and Focal, operating expenses increased just 2.7%, reflecting strong expense discipline, especially in G&A. We continue to balance growth investments with our goal to drive operating leverage, and our R&D pipeline has never been more productive than it is today. Based on improvements in the top line and strong operating discipline, operating margins of 29.4% increased 30 basis points. Operating margin also improved sequentially to our best level since the fourth quarter of 2017.

Other expenses net totaled $33 million in the fourth quarter. As Steve explained, this line included our share of SSI results, specifically a loss of $1.8 million, which was not contemplated in our most recent guidance. Other expenses also benefited from gains from our currency hedges. As a reminder, these hedges reset back to zero in 2020, assuming currency stay flat.

Finally, net margins of 20.2% increased 70 basis points compared to the prior year period, our best result since the third quarter of 2016. In addition to better operating margins, we had slightly lower effective tax rate, which effectively offset the loss from SSI. Overall, our net profitability remained very healthy. All this led to non-GAAP net income of $175 million in the fourth quarter and non-GAAP earnings per share of $0.65, in line with our forecast.

On a GAAP basis, we posted EPS of $0.15, lower than expected due to non-cash impairment charges, totaling $79.2 million related to Medical Aesthetics. As Steve noted, not much has changed in this business, but we've looked at these charges as part of our normal year end accounting process of reviewing long lived assets for impairment.

Before we move on to our initial 2020 guidance, I'll quickly touch on a few other key financial metrics. Our leverage ratio stood at 2.3 times at the end of the fourth quarter. We remain comfortable around this level, recognizing that the ratio could fluctuate based on the timing of acquisitions and buyback activity. The combination of strong profit growth and net debt improved our return on invested capital. As of year-end, ROIC was 13% on a trailing 12 month basis, an increase of 40 basis points over the prior year. Finally, in the fourth quarter, adjusted EBITDA improved to $277.7 million, an increase of 5.5%.

Now, I'd like to discuss our initial non-GAAP financial guidance for fiscal 2020. Before I do, let me remind you that, as usual, there are several puts and takes in comparing 2020 to 2019. In terms of headwinds, revenues from our divested Blood Screening business is expected to decline significantly in 2020, and in foreign exchange rates at recent levels will be a drag on reported results of about $70 million, or roughly 50 basis points on the company overall.

On the positive side, the acquisition of SuperSonic Imagine will represent a tailwind to reported revenue growth in 2020. Our guidance assumes that SSI's revenue and operating results will be consolidated into Hologic's financials at the beginning of the second quarter with revenues totaling $25 million to $30 million for the nine months. Current Street estimates include a wide range of timing scenarios. So hopefully, this guidance will help with modeling.

For the first quarter, we have assumed our portion of SSI's loss, and as a reminder, SSI will be slightly diluted to non-GAAP EPS for the full year as we said when we announced the deal. As you update your forecast, we encourage you to model at the middle of our guidance ranges at this early stage as we've tried to set realistic ranges that incorporate, both potential upsides and downsides.

We anticipate that fiscal 2020 will be a good year for Hologic overall. Specifically, we anticipate constant currency revenue growth of 3% to 4.5%, in line with our improved organic performance in 2019. If we meet the high end of this range or exceed it, organic revenue growth should accelerate compared to 2019. Based on recent exchange rates, our top line guidance translates into reported growth rates between 2.5% and 3.9% and sales of $3.45 billion to $3.5 billion.

We expect tuck-in acquisitions to continue being an important part of Hologic story going forward, and believe that additional deals will boost revenue in 2020. But as we think about our organic growth rate, I would point out that the blood screen headwind and the SSI tailwind that I previously discussed basically offset each other next year. Said another way, our organic growth rate should be similar to the constant currency growth rate of 3% to 4.5% in 2020, depending on how you model the various components.

In terms of global division, our guidance contemplates similar growth rates in diagnostics, excluding Blood Screening, Breast and Surgical in the lower part of mid single-digits. We forecast less growth in Skeletal and Medical Aesthetics. Within these estimates, international revenue should grow in the high single-digits on a constant currency basis, in line with 2019, as we continue to see opportunities to drive sustainable growth in multiple markets across all our businesses.

In Diagnostics, Molecular should continue to lead the charge in 2020 behind Panther Fusion and increased utilization of more than 15 women's health virology and respiratory assays. We anticipate $30 million to $35 million of revenue from the divested Blood Screening business, much lower than in 2019.

In Breast Health, growth will be driven by multiple new products, accretive growth from Faxitron and Focal, our International business, three quarters of SSI results, and a large service annuity that now totaled well over $450 million annually. In Surgical, we expect growth from the continued expansion of MyoSure, the stabilization of NovaSure, the new products Steve discussed and International. In Medical Aesthetics, we expect growth from an increasingly productive sales force and new products, including TempSure Affirm and StimSure, which we've recently launched in Europe.

In terms of profitability, we forecast gross margins to improve to 61.6% in the full year 2019. We expect better margins due to lower manufacturing cost, improved product mix, absorption benefits, the ramp of new product sales and our ongoing cost reduction efforts. These benefits will be partially offset by the expansion of our international business, which adds gross margin dollars but pressures our gross margin percentage.

In terms of the quarter, we forecast that gross margin percentage will increase sequentially as the year goes on, based on the mixed benefits from newly launched products and higher overall revenues. In terms of operating expenses, we expect to continue showing strong leverage that helps drive healthy growth and operating margin percentage and ultimately EPS, even as we absorb an incremental $8 million in costs related to the new European MDR and IVDR regulations.

Our guidance does not, however, include a re-instatement of the medical device excise tax, consistent with Street's current modeling and our expectations that it will be suspended again. Below the line, we expect other expenses net to be greater in fiscal than the roughly $130 million we recorded in 2019, primarily due to the absence of foreign currency hedge gains based on recent exchange rates.

All this leads to forecasted earnings per share between $2.60 and $2.65 in 2020. This represents reported growth of between 7% and 9.1%, about double the rate of revenue growth, despite EPS headwind from currency and diminishing contributions from our divested Blood Screening business. We expect quarterly EPS to ramp up sequentially as the year progresses as it did in 2019. This guidance assumes a full-year tax rate of approximately 21.75%, flat to 2019 and diluted shares outstanding of about $272 million for the year. We also expect to continue generating robust free cash flow in 2020 in the mid $600 million range, excluding one-time items.

Now let's cover guidance for the first quarter of fiscal 2020. We expect revenues of $835 million to $850 million in the quarter. This reflects constant currency growth of 1% to 3% and reported growth of 0.5% to 2.3%. As a reminder, our Breast Health business performed exceptionally in the first quarter of, 2019 which contributes to lower growth rate this year. And most years, Breast Health is seasonally weaker in the December quarter due to RSNA and the holidays. We forecast non-GAAP diluted earnings per share of $0.59 to $0.61 in the first quarter, representing 1.7% to 5.2% growth on a reported basis.

Before we open the call up for questions, let me conclude by saying our fourth quarter capped off as successful year for the company. Our largest businesses, Breast Health and Molecular Diagnostics, led the way and Surgical continued to improve, driving revenue outperformance overall. We are encouraged by the continued strong commercial execution, the progress in our international franchises, the productivity of our R&D pipeline and the deals we have completed. We continue to exercise tight expense controls and strategically redeploy capital. Overall, we feel confident in our foundation heading into 2020, and have the leverage to deliver healthy revenue and EPS growth.

With that, I will ask the operator to open the call for questions. Please limit your questions to one plus a related follow up. Then return to the queue. Operator, we are ready for the first question.

Question-and-Answer Session

Operator

[Operator instructions] And we'll hear first from Tycho Peterson with JPMorgan. Please go ahead.

Tycho Peterson

I'll start with guidance. Steve, you haven't really backed up the notion that you can be a mid single digit growth company. Obviously, you're getting a little bit below that. But given the kind of state of new product launches that you highlighted on the call, it seems like the bias would be maybe towards the higher end of guidance. So are there things that are actually going to be a little bit of a drag on growth as we think about next year. And then can you talk a little bit about which of the new product launches could be most incremental for next year?

Steve MacMillan

Tycho, make no mistake, we feel really good about the zip code or getting into here in terms of organic growth. And certainly if you look in this most recent quarter, the number was well above where we've been. We just don't want to get too far ahead of ourselves. It's kind of like we had a great first quarter to the year 13%. We're about to go against 13.5% comp in Breast Health and 11% in Molecular Diagnostics as we start the year. So we just don't want to get too far ahead of ourselves. But don't mistake that for confidence in the underlying growth in the business, all the new products coming through, building quarter-upon-quarter Surgical bouncing back and getting stronger. So I think we feel very good. We're just this is coming out of the gates. It's certainly an uncertain global economy and everything else right now, there's no sense with us being too far ahead of ourselves. But don't mistake the guidance for how we feel about the business.

Tycho Peterson

And then from the follow-up question on margin leverage, first of all, Karleen, you called that the tariffs hit on gross margins. I'm wondering if you can kind of quantify that. And as we think about 2020, just curious where you see the operating margin levers from your perspective?

Karleen Oberton

So I think the first part of your question, Tycho, that we've quantified the China tariffs around $10 million annually as the headwind. And as we look at operating margins into 2020, we do expect leverage when we expect gross margins to improve, we expect higher revenue. And we do believe there's still opportunities in the middle of the P&L, especially as we integrate recent acquisitions to contribute to the margin growth.

Operator

Thank you. We'll now take our next question from Bill Quirk with Piper Jaffray.

Bill Quirk

So I guess first question, Steve, kind of bigger picture. I appreciate that that the capital exposure in the model is much less than it once was. And we're still hearing some pockets of potential capital softness, typically in the U.S. I'm just curious what your thoughts are at present?

Steve MacMillan

I think as one of the few people who is running a company through the last major economic meltdown, as you know, [Bill Moyers] can be a little more cautious. And having said that, I think we feel better and better about the sustainability of our business. First off, we're so much less dependent on capital. Our diagnostics business, our surgical businesses, these are all recurring revenue and increasingly, our Breast Health business, between the gantries are a smaller and smaller portion of that.

The service business is big, the additional product upgrades and those kinds of things that are smaller outlays, that can be funded out of operating expenses from the hospital budgets. I think we feel very, very good about the likelihood of continued growth within the businesses. And the fact that we've really transformed what the company looked like certainly going into the last downturn.

Bill Quirk

And then as a follow-up, just following up rather on one of the diagnostic comments you made about the average utilization for Panther. Can you remind us where you are in percentage terms on average? I seem to recall that we were at something like 40% to 50% utilization on the systems. And then just briefly, kind of how high can that go? Is about 80% as good as it gets and then you're looking at a second system? Thanks.

Steve MacMillan

Sure. Not to get too granular with it, Bill. I would say in the U.S., we're certainly seeing numbers probably above that, and outside the U.S. still below that 40-ish percent number. So we still have a lot of runway ahead of us. And I think part of what we feel really good about is the continued placing of the Panthers. And the way we keep thinking about this is, keep placing more and more Panthers each year, another 200-ish last year. And then as you know, we're putting more and more menu onto each Panther, both domestically and internationally.

So there's still a long way to go without us having to place an enormous amount of additional Panther. So a lot of the capital has already been made. That's been part of the gross margin issue even internationally as we've been placing more of the Panthers, and then that will recoup and it will be part of our margin expansion story in the years ahead.

Karleen Oberton

Just to add to that, we look at certain key international markets. We only have one or two assays approved on the Panther. And as we peruse additional regulatory approvals, that will drive that increased utilization and the margin expansion that Steve mentioned.

Operator

Thank you. We'll take our next question from Jack Meehan with Barclays.

Jack Meehan

I wanted to just focus on Diagnostics business. Obviously, pretty strong in molecular. I was just curious what you thought the runway was like for placements in the U.S. just based on the math around 1,700 in the overall 45% U.S., last year was 1,500 about 40 -- I'm sorry, that was international, 40% international was last year. It just seems like a lot of the placements were international over last year. So what's the runway for placements in U.S.? And maybe just more broadly, are you seeing any signs of consolidation amongst labs and how might that impact kind of the runway for Panther?

Steve MacMillan

Jack, I think highest level we're probably in the 7th-ish inning in the United States, so a little earlier internationally. But I think still some significant opportunities, particularly with our largest customers. To your second point, lab consolidation, I think, that's an inevitable that we expect to continue to see. I think part where we feel great about the relationships that we've cultivated very deep relationships, obviously, with the largest players in the United States. We continue to work very closely with them to help both drive categories, volumes. And as they are really the consolidators, you know, we will benefit certainly from a volume standpoint going forth.

Mike Watts

Jack, this is Mike. If I can just add one thing to that about the U.S. market. As Steve said, we have placed a lot of Panthers in the U.S. But we have, I think 15, 16 different tests approved on Panther domestically and only about half of our customers use more than two assays. So there's lots more room on board those systems to layer additional menu as it gets approved and it's already approved.

Jack Meehan

And that was going to be my follow-up question is, I think I caught sexual health grew high single digits overall. So I wondering if you could just give us some mark-to-market in terms of what the virology versus Fusion slits, you know how just looking at 2019 what the total was for the year and what the balance within the molecular forecast assumes for those continuing to expand?

Steve MacMillan

Yes, I mean that's a lot of detail there, Jack. We probably aren't going to go quite that far. I mean, I think we talked about virology a year ago being in the $20 million range. I don't think it quite double, but kind of close to that in the most recent 2019. Fusion is off to a good start, ramping off of base but that base is much smaller than that.

Operator

Thank you. We will hear now from Ivy Maa with Bank of America.

Ivy Maa

I guess just a broad question to start off. Can you talk more about the OUS trend? You're talking about investing more in OUS to extend the base, which might have some impact on the margin. So wanted to see what the opportunity there, what still out there untapped or still was the largest opportunities out there? Thank you.

Steve MacMillan

Sure, Ivy, I think as we look at it, we see tremendous opportunities for all of our franchises in all of the major geographies. I think we really put more of a footprint down in Western Europe over the last few years where we now have -- we've gone direct in the Breast Health business, really in the UK and in Portugal, Spain, Germany, Switzerland, Austria, we still use dealers in most of the rest of Europe. But I think we've really built a competency there.

Our Diagnostics business, we've gone more and more direct in those businesses. And Surgical, we're really just getting started. We're really only had a few countries in Europe and starting to build that business out as well. Shifting over Asia Pac, it's really a fairly similar story. The biggest underdevelopment, candidly, is Japan, that will take longer certainly to build out just given the fundamental dynamics, particularly in the Breast Health space there. But I think we're seeing very nice progress across the diagnostics business, including Cytology, and big opportunities in Breast Health in diagnostics and surgical certainly over time as well.

So I think the way we think about it is, each year we're building a few more competencies and it's not going to be something you're going to see an inflection point, but consistently growing at an creative rate to the overall company.

Karleen Oberton

I would just add some comments I made early. The opportunity is clearly expanding the assay menu in key countries internationally is going to drive growth. And as well as on the Breast Health business compared to the U.S., we are still converting from analog to 2D, not just 2D to 3D, so continued long runway for our key products.

Ivy Maa

And just to follow up on that. Karleen, you talked about the margins, there're lot of puts and takes in the margin trends for next year. Can you provide any sort of constitution if you can for those myriad of sectors? Thanks.

Karleen Oberton

So I think maybe you're referring to gross margins. There was a lot of puts and takes in the results, more takes I think than we expected. As we look to 2020, I think we're thinking about a range of gross margin expansion of about 50 basis points to 100 basis points. And as I talked about, we believe that will build as the year goes on in that from an operating margin perspective probably a little bit from that.

Operator

Thank you. We'll hear now from Doug Schenkel with Cowen.

Chris Lin

This is Chris on for Doug. Thanks for taking my questions. Just want to start with another question on Europe. Given the mixed macro backdrop in Europe, curious if you have seen any order softness, especially for the more capital oriented businesses?

Steve MacMillan

We are not seeing any softness in Europe at the moment. I'm always a little nervous between Brexit, between everything else you have going on there, but we've been planning, and preparing. And I think for us we just continue to feel like our teams are getting stronger and stronger there. So feel good about our outlook. And really, I can't tell you how excited we are by our team in Europe. They have just come so far in the last few years.

Chris Lin

And then maybe a question on Breast Health, I think you've been tracking 250 to 300 placements in the U.S. Sounds like maybe it was above down in Q4. Maybe just help us think about the right way to model the gantry placements in 2020 for U.S.

Steve MacMillan

I think, we see it pretty much in that range. And we go back to four years ago or so when we said we were intent on breaking the cycle, and the job Pete Valenti and our U.S. team has done has been truly breakthrough and breaking that cycle. And I think what we've gotten into is much more of a steady cadence of replacement cycle that we had articulated we saw coming years ago, and it was our attempt to doing. So I think it's kind of settling into that range, which works out pretty well because the positive for that is it still gives us years ahead, I think everybody can see from the MQSA data that's available. We're clearly gaining far more in the competitive set than just upgrading our -- so I think still gives us years of runway ahead of us here, plus then being able to go back and get additional revenue from mining the install base further. But I think that's a rough way to think about it.

Operator

Thank you. We'll now move on to next question from Vijay Kumar with Evercore ISI.

Unidentified Analyst

This is [Luke] on for the Doc. Just quick on Breast Health, so you guys had a great quarter there. And just thinking about it and as just talked about the place coming in a bit ahead and the overall macro uncertainty in the 2020. Do you guys see any pull forwards there on the CapEx side?

Steve MacMillan

We have not, Luke. I think we kind of wondered about that a little bit in our fiscal first quarter of last year when Breast Health was really strong, but haven't really seen much to that effect at this point in time.

Unidentified Analyst

And then I guess Cynosure, the next one, the Aesthetics business, returning to flat to growth ex the items in '18. So the outlook in there for '20 you guys are expecting that to kind of accelerate. How should we think about that in Q1? And is that something that's going to build over the quarters, or should that be pretty stable?

Steve MacMillan

Keep the expectations down there. I think it'll build over the year because of the way the product pipeline is shaping up. We've got some things coming that probably won't quite hit in our fiscal first quarter, but should hopefully start to hit as we go into frankly the new calendar year. So I think we feel certainly better about the build on that business through the year.

Operator

Thank you. We'll take our next question from David Lewis from Morgan Stanley.

Mason Austen

This is Mason on for David today, thanks for taking my question. You referenced stabilization of NovaSure in fiscal '20. Does that mean you're expecting this business to grow next year? And any updates on the competitive environment you can provide?

Steve MacMillan

We're not declaring that we see that business, that NovaSure itself growing necessarily next year. We do feel great about the trajectory of the surgical business.

Mason Austen

And your share count guidance doesn't incorporate any significant amount of buybacks, it looks like. But over the past couple of years, you've repurchased about 5 million to 7 million shares a year. Does this mean we should signal an uptick in M&A activity this year, or how should we think about capital deployment balancing? Thank you.

Karleen Oberton

So I don't think anything's changed capital deployment strategy really between tuck-in M&A and share repurchase. I think from a guidance perspective, we just assumed a minimal share repurchase to manage dilution. As we just sit here today it's early and where the deal flow will play out.

Operator

Thank you. We'll hear now from Raj Denhoy with Jefferies.

Q - Anthony Petrone

This is Anthony for Raj. Just quick one on guidance and then a couple on Breast Health. Just on guidance, SuperSonic image SSI. I'm just wondering what's baked in there for 2020 at the guidance line and just follow up on Brest Health? Thanks.

Karleen Oberton

Sure, Anthony, this is Karleen. So what we've said is as you know, we don't own a 100% of that today. We're tender offer process. So what our guidance assumes is that we will have revenue from SSI for the three quarters Q2 to Q4 in a range of $25 million to $30 million. We also assume that for Q1 we'll have our portion of their loss as well in Q1, but no revenue or expenses.

Anthony Petrone

And just on Breast Health. Just wondering if there is an update on the FDA proposal around dense breast screening. Just when do you think the timing would be for final rule? And what do you think really that means for 2020 within Breast Health should the final rule call for more imaging robust imaging and screening for dense breast patients? Thanks again.

Steve MacMillan

Sure Anthony. I'm probably owed for my lifetime on exactly predicting those kind of things out of FDA. I think what we do feel great about is what we control, which is we are the only 3D with the dense breasts indication, that is helping us when new business all of the time as people see that we're the ones that have that. Whether that guideline comes through from FDA in 2020 or not, exactly when it comes through, we don't see it as having necessarily a material uptick in our business, other than a further reinforcement of where the business is going.

Mike Watts

And as a reminder, Anthony, that's been going on at the state level in a bunch of states for quite some time, so that contributes to what we're seeing as well.

Steve MacMillan

It's clearly a net positive for us.

Operator

Thank you. We will take our next question from Brian Weinstein with William Blair

Andrew Brackmann

This is actually Andrew Brackmann on for Brian. Brian wanted to be on the call, Steve, but he's out celebrating Bears win over the Eagles in the second half of that game. Maybe just on…

Steve MacMillan

I thought Brian was actually going to be at the open tryouts at the Bears that they're having.

Andrew Brackmann

His leg's not too good. I heard they need a kicker.

Steve MacMillan

Well, then he can math every other kickers. All right. Back to our regular scheduled program…

Andrew Brackmann

Yes, exactly. On Breast Health, Steve, you mentioned the artificial intelligence product sort of rolling out through 2020. Any additional detail you can provide on what sort of impact that might have this year and then sort of the lever you think it can provide to the company over the next several years?

Steve MacMillan

Sure. I think it will be less in terms of meaningful acceleration or anything like that. I'd just be more of the products where we're starting to sell, like Clarity HD, our SmartCurve paddle we were able to start to monetize additional software into the gantries and into our sales. But over time, we think it's going to help establish that much more of a moat around our business by being the leaders to leverage the largest base install base in the business.

So I don't think you'll be able to meaningfully break out that AI products are going to add ex million of growth, but they will start to dribble in here later on in 2020 and then start to contribute more in 2021 and beyond.

Andrew Brackmann

And then just a clean-up question on the Brevera issue, I may have missed it. But any update on when that when that might be behind you guys? Thanks.

Steve MacMillan

I think it'll likely be later this year. Our expectation is we will be back on the market with new capital, probably in our fiscal fourth quarter. So we should be there so. so, give Brian our best.

Operator

[Operator instructions] We'll now hear from Dan Brennan with UBS.

Dan Brennan

I just wanted to ask a question first, Steve, on molecular. So what's baked in for 2020 growth? Is the high single digit consumable sustainable? And can you comment on kind of the competitive dynamics in that market?

Steve MacMillan

I think as we think about the growth rate for molecular next year, probably smart to think about it is in the mid singles and then gaining pushing upwards towards high singles. Certainly, we're going to be going against some really tough comps, especially the first three quarters this year against global double digit numbers. So I think it will still be very strong growth in that space.

I think for the competitive environment, we feel pretty good that we continue to innovate. And as we are rolling out more and more assays, that business should certainly be good. So we've guided our overall diagnostics businesses, as Karleen said, probably in at least the low mid single digits. So Molecular will clearly be leading above that.

Dan Brennan

And then maybe to follow up just on M&A, the tuck-in strategy has been working well. It sounds like there will be more to come. So can you just give us some color on the appetite to maybe do anything bigger, kind of, how should we think about kind of the level of maybe the size of deals that we should expect going forward now that you've successfully executed a bunch of these? Thanks.

Steve MacMillan

Sure Dan. Actually really glad you asked that, because probably what's been under appreciated is, we've really shifted from a, what's been a corporate led business development strategy for what had been most of the 2000s and frankly up, even up to the Cynosure deal. But over the last few years, we've really built the divisional lead tuck-in capabilities. And I think we're just starting to really see what we'll be able to do there.

In terms of magnitude, would not expect us to exceed, for example, our annual cash flow in terms of rough amount of deals. So, I think we're definitely in the tuck-in mode. There will certainly probably be a few that could be bigger than $100-ish million deals that we've done to-date, but nothing that's going to blow the mind or anything. I think we like really frankly being able to both do some acquisitions and do some stock buybacks within each year. And while not a formal policy, it's something we've discussed quite a bit as a management team and our board of really being able to use the natural cash flow that we have each year as opposed to needing to lever up or take on something more. And I think we've now seen there's more opportunities within our core businesses, and things that we're excited by. So thank you.

Mike Watts

Cody, I think about that and that's about all the time that we have. So thanks everybody for your time on the call today, and we will talk to you all soon.

Operator

Thank you. That concludes Hologic's fourth quarter fiscal 2019 conference call. Have a good evening.