12-Aug-2021

Organon & Co. (OGN)

Q2 2021 Earnings Call

CORPORATE PARTICIPANTS

Jennifer Halchak
Vice President-Investor Relations, Organon & Co.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

OTHER PARTICIPANTS

Terence Flynn
Analyst, Goldman Sachs & Co. LLC

Navann Ty
Analyst, Citigroup Global Markets Ltd.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Matthew Harrison
Analyst, Morgan Stanley & Co. LLC

Umer Raffat
Analyst, Evercore Group LLC

Steve Scala
Analyst, Cowen & Co. LLC

MANAGEMENT DISCUSSION SECTION

Operator: Good day and thank you for standing by. Welcome to the Organon Second Quarter Earnings Conference Call. At this time all participants are in listen-only mode. After the speakers' presentation there will be a question-and-answer session. [Operator Instructions] Please be advised that today's conference call is being recorded. [Operator Instructions]

I would now like to hand the conference over to your speaker today, Ms. Jennifer Halchak, Vice President of Investor Relations. Please go ahead.

Jennifer Halchak

Vice President-Investor Relations, Organon & Co.

Thank you, Rayne. Good morning everyone. Thank you for joining our second quarter 2021 earnings call. With me today are Kevin Ali, Organon's Chief Executive Officer and Matt Walsh, our Chief Financial Officer. Today, we'll be referencing a presentation that will be visible during this call for those of you on our webcast.

This presentation will also be available following this call on the Events and Presentations section of our Organon Investor Relations website at www.organon.com. Before we begin I would like to caution listeners that certain information discussed by management during this conference call will include forward-looking statements. Actual results could different materially from those stated or implied by forward-looking statements due to risks and uncertainties associated with the company's business which are discussed in the company's filings with the Securities and Exchange Commission including our Form 10 and subsequent SEC filings.

In addition, we will discuss certain non-GAAP financial measures on this call which should be considered a supplement to and not a substitute for financial measures prepared in accordance with GAAP. A reconciliation of

these non-GAAP measures to the comparable GAAP measures is included in the press release and conference call presentation.

I would now like to turn the call over to our CEO, Kevin Ali.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Good morning, everyone and thanks again. Welcome and thank you for joining us today. As you may know, for several years in the making, Organon officially spun from Merck on June 2 and began trading as a public company on June 3. So today marks our first earnings call as a standalone public company and I'm very pleased to be here.

Organon's vision is to create a better and healthier every day for everyone. We have seen how our vision and purpose has connected with so many and continues to motivate thousands of our employees who've been hard at work standing up Organon and at the same time have been focused on driving our business. In the second quarter, Organon generated $1.6 billion of revenue, $627 million of adjusted EBITDA and $1.72 in adjusted earnings per share.

Year-to-date, all three of our franchises are delivering on their objectives, each playing their role in driving our vision of improving the health of women. Accordingly, today we affirmed the full year 2021 guidance we provided at our May Investor Day. Looking out past 2021 we remain confident in our ability to grow revenue low to mid-single-digits on an organic basis as LOE risk will largely be behind us and the women's health and biosimilar franchises are positioned to deliver double-digit growth.

Today, we also announced an important milestone for Organon. Our board of directors has declared a quarterly dividend of $0.28 per share, which speaks to the cash-generating power and sustainability of our business.

Turning to slide 5 now. Though new as a stand-alone company, the 64 products that came to Organon from Merck are trusted, well-recognized medicines, many of them household names. We operate in three franchises. Women's health and biosimilars are two growth engines, and Established Brands, which is a portfolio of 49 products that generate sizeable and stable cash flows even though most have already lost exclusivity.

Organon endeavors to be a different kind of company, one focused on advancing the health of women. In order to do that, we are broadening our portfolio beyond our already market-leading positions in contraception and fertility. We've already begun to execute on this vision, already completing two transactions in important areas of unmet needs for women.

In June, we completed our acquisition of Alydia Health, which is a commercial stage medical device company that received a 510(k) clearance from the FDA in 2020 for the Jada System, a product intended to control abnormal postpartum bleeding or hemorrhage. We plan to use our global commercial footprint in reproductive health and experience in creating affordable access and to further develop and bring the Jada System to more women around the world.

We recently also announced a licensing agreement with ObsEva for the global development, manufacturing and commercial rights to investigational agent ebopiprant, currently being studied as a potential first-in-class innovation for the treatment of preterm labor. To remind everyone, every year, 15 million babies are born preterm. And although preterm birth rates are on the rise, there are currently no other known compounds in development and no approved therapies for the acute treatment of preterm labor in the United States. As our first development

stage asset, Organon intends to leverage its considerable expertise and work with the scientific and medical communities and regulatory authorities in major markets including the United States to advance the clinical development and registration of ebopiprant.

Both of these opportunities falls squarely in line with our business development strategy in size, scale, market opportunities and to our focus on helping address the most serious unmet needs of women. Our early progress demonstrates how serious we are about our commitment to becoming the leader in women's health and expanding our portfolio beyond contraception and fertility.

Turning to slide 6 now, we can't talk about our women's health portfolio without talking about NEXPLANON, the number two contraceptive worldwide by revenue and a product we believe has blockbuster potential. Now, NEXPLANON plays in the LARC market or otherwise known as the long-acting reversible contraception segment. Globally, the hormonal contraception market continues to see usage shift away from the daily combined oral contraceptive segment towards LARCs. LARCs are highly efficacious and considered to be one of the most effective forms of hormonal contraception available.

NEXPLANON or Implanon NXT as it's known in some markets is differentiated even within the LARC segment as it's the only single rod subdermal, long-acting, reversible contraceptive. It is a progesterone-only rod that is inserted in a woman's upper arm. Average insertion time takes about a minute, and it is conducted in the health care provider's office.

NEXPLANON has exclusivity in the US until 2027 and until 2025 in markets outside of the US. Currently, NEXPLANON is approved for three years of efficacy. But in November 2020 we began a registration study to evaluate the use of NEXPLANON for up to five years. If successful, we believe this will make NEXPLANON an attractive contraception option for many more women including those who are family complete.

During the quarter our fertility portfolio also showed particular strength. We're very encouraged by the early traction especially in China where fertility demand is very close to being back to pre-COVID levels. Governments around the world are becoming increasingly active in addressing the fertility issues families can face. Recently, the Chinese government introduced the three-child policy. And next year, Japan will introduce reimbursement for IVF treatments in an attempt to address declining birth rates. The French government also recently passed a bill to allow egg freezing and for same-sex couples to seek IVF treatment.

Outside of women's health, we're also encouraged by the growing support for biosimilars. The US biosimilar market continues to grow with increases in physician and payer comfort with biosimilars. Both of the therapeutic areas we compete in, namely immunology and oncology, are seeing increased biosimilar utilization, though oncology conversion from originator to biosimilars has been faster.

For example, trastuzumab, which is where ONTRUZANT plays, has some of the highest adoption rates among biosimilars. We currently see nearly 70% of the trastuzumab market converted to biosimilars. We're well-positioned in the biosimilar market as a commercial collaborator with Samsung Bioepis.

We have a good balance in terms of geographic contribution, so we're not levered to the particular dynamics of any single market. We have balance with the lifecycle of our portfolio. And we have marketed products that are growing, like RENFLEXIS and ONTRUZANT.

We have launched assets like HADLIMA in Australia and Canada, which are performing very well. And we have what we believe will be a major pipeline opportunity with our anticipated HADLIMA launch in the US in 2023. We also continue to evaluate other potential pipeline opportunities with Samsung as well as other partners.

And as we think about our established brand portfolio part of the strategic timing of the spin is that 2021 is an inflection year. It is the last year during which the portfolio is subject to significant new LOE risk. Beyond 2021, the impact from the LOEs dissipates.

Further, we have opportunities to soften the erosion curve with continued growth of ATOZET launched as a serving product in selected markets and other lifecycle management opportunities. We continue to take an entrepreneurial view with regards to the established brand portfolio. And all three franchises are global businesses, as you'll see on the next slide.

Asia Pacific was the only geographic region that was down in the quarter and that was driven by ZETIA's loss of exclusivity in Japan. Our largest region, Europe and Canada, is showing strong double-digit growth driven not only by COVID recovery, but also by volume growth in biosimilars and in fertility.

The US, particularly NEXPLANON, benefited from lapping the significant COVID impacts in the second quarter of last year, but also from growth in fertility. The US also showed solid performance in biosimilars, where we offer both RENFLEXIS and ONTRUZANT.

In China, we had several positive areas of momentum that more than offset the impact from four of our products being included in the volume-based procurement process in the fourth quarter of last year.

We also saw the respiratory market recovering from the negative COVID impact in 2020. Our fertility portfolio outpaced the market in Q2, and the contribution from the retail channel continued to grow. We're actively monitoring the impact of COVID and its variants across the world, but overall we are very encouraged by how the portfolio is performing.

And now, I will turn it over to Matt to discuss our second quarter performance in more detail. Matt?

Matthew M. Walsh

Chief Financial Officer, Organon & Co.

Thank you, Kevin. Before I review the details of the quarter, it's important to remind everyone that our second quarter is unique and it's, what I would call, a hybrid quarter. It's hybrid, in that Q2 includes approximately two months of pre-separation operations for which GAAP mandates the carve-out method of accounting and approximately one month of post-separation business activity accounted for by conventional GAAP methodologies. But the key area of commonality across these two different methods is revenue, which is presented, by and large, on an apples-to-apples basis; and that's where I'll focus most of my commentary.

So with this clarification on basis of presentation, and now let's turn to slide 8, and revenue for the second quarter was up 4.5% (sic) [5%] as reported and down about 1% at constant currency exchange rates. The impact of the loss of exclusivity, or LOE, during the second quarter of 2021 compared to the second quarter of last year is approximately $130 million and it's primarily related to the loss of exclusivity of ZETIA in the back half of 2020 in Japan, as Kevin mentioned, and NuvaRing's LOE in the United States.

The Established Brands portfolio has exposure to the volume-based procurement initiative or VBP in China. The total impact to sales for the second quarter compared to the second quarter of last year was approximately $40

million and was associated with the third round of VBP, which is the largest so far and which occurred in the fourth quarter of 2020, and that included four of Organon's products: SINGULAIR paediatrics, PROSCAR, PROPECIA, and ARCOXIA.

In the second quarter of 2021, the negative impact of COVID-19 was estimated to be approximately $120 million, which is about $100 million better than last year. Our product portfolio is comprised of physician-prescribed products which have been affected by social distancing measures and fewer medical visits. And although we believe that global health systems and patients continue to adapt to the evolving impacts of the pandemic, and although we have experienced recoveries during the second quarter as compared to the year-ago quarter, we do expect that ongoing negative impacts will persist through the remainder of 2021.

Foreign exchange translation had a fairly sizable impact in the second quarter, with about 550 basis points of favorability. And it's not really surprising given the impact of COVID-19 on global currency markets in the prior year period, and also understanding that approximately 80% of Organon's revenues are derived outside the United States.

And finally, we are seeing volume growth mainly driven by our key growth businesses, women's health and biosimilars, as well as growth geographically in China, in fertility and in our Established Brands products ex-VBP.

So now, let's take a look at performance by franchise, and we'll start with women's health on slide 9. Our women's health business grew 19% as reported and 16% ex-FX in the second quarter. We saw a growth in NEXPLANON, which was up 39% ex-FX in the quarter and benefited from patients beginning to return to their healthcare providers as COVID-19 restrictions are lifted.

Now while in-person patient visits to healthcare professionals demonstrated recovery in the second quarter relative to the height of the COVID-19 pandemic during the same period last year, they're not yet back to pre-pandemic levels. And as a result, we expect that ongoing negative impacts will persist through the rest of 2021. And that view is incorporated into our guidance, which we'll discuss shortly.

Our fertility portfolio is showing strength. FOLLISTIM grew 40% in the quarter. Volume growth came from increase in demand from new accounts, as well as from patients returning to clinics. We have observed that patients seeking fertility treatments are more motivated to return to doctors' offices than those patients seeking normal course well visits. So, these growth drivers more than offset the 19% decline in NuvaRing related to increased generic penetration as a result of NuvaRing's LOE in 2018 in the US.

Turning now to biosimilars on slide 10, biosimilars grew 43% as reported in the second quarter and 35% ex-FX. We have five assets in the portfolio, three in immunology and two in oncology. We launched our first asset, BRENZYS, in 2016, followed by RENFLEXIS in 2017, ONTRUZANT in 2018, and AYBINTIO in the back half of 2020. HADLIMA launched this year in Australia and Canada.

RENFLEXIS and ONTRUZANT are our two largest offerings and both are offered in the United States. Globally, RENFLEXIS grew 38% ex-FX in the quarter, driven by strong performance in the US, and ONTRUZANT, which was launched in the US in July of last year, was up 13%.

Turning to Established Brands now on slide 11, because of a number of products in Established Brands in the multiple markets in which they're sold, we'll often discuss the performance of this franchise in terms of how it behaves as a portfolio. So, revenue for Established Brands was down 4% as reported and 10% ex-FX in the second quarter of 2021. Excluding the impacts of LOE, revenue was down about 2% ex-FX. Volumes were up

incrementally, mainly driven by COVID rebound, and price was down about 2%, which is consistent with our prior disclosures and that we expect price erosion in Established Brands to be in the low-single digits ex-LOE over the intermediate term.

China is an important market for Established Brands, and part of our strategy in this market has been to move business out of the hospital channel and into the retail channel, and this effort continues to be successful. The retail channel in China grew double digits, and now represents about 45% of Established Brands revenue in China, up from approximately 35% a year ago. And just a reference, total revenue in China across all Organon business lines for the second quarter was $236 million, up 12% versus the second quarter of last year.

Now, turning to our income statement on slide 12, again, because of the hybrid nature of this quarter, comparability to prior year performance across most income statement line items is not particularly meaningful, we can, however, draw comparisons at the revenue and gross margin lines if, in the case of a ladder, we make a sensible adjustment to exclude purchase accounting amortization and onetime items from cost of goods sold.

So making this adjustment, in the second quarter of 2021, non-GAAP gap adjusted gross profit was $1.044 billion, representing gross margin of 65.5% compared with 71.2% in the second quarter of last year. The decline reflects an increase in standalone costs, including certain costs related to manufacturing agreements between Organon and Merck, which have lower gross margin percentages compared to third-party product sales.

While comparison to prior year performance were challenging, probably the most important commentary we can make about Q2 performance is that it aligns very well with the full-year guidance for 2021 that we provided at our Investor Day across all line items of our P&L, from revenue down to adjusted EBITDA, and including our non-GAAP effective tax rate. And we'll come back to guidance in a few moments.

A few words on debt capitalization, at June 30, our bank debt was $9.5 billion against cash and cash equivalents of $730 million, although this cash balance includes about $400 million of pre-funded cash that will shortly be remitted back to Merck related to pre-spinoff inventory conveyance that will actually occur post-separation. So, a more representative net debt number is actually closer to $9.2 billion.

And if we think about leverage ratios in the context of the guidance that we're affirming today, and just to be illustrative, if we use the midpoint of our implied 2021 adjusted EBITDA guidance, that would put our net leverage ratio just below 4 times.

We discussed our capital allocation priorities at our Investor Day in May, and I'll repeat them here today. With a recurring dividend now declared, of course, the dividend becomes capital allocation priority number one. We've endeavored to set the dividend at a low-20s percentage of free cash flow, excluding onetime cost of the separation, and this level, we believe, will be very manageable going forward.

Our second priority will be organic growth, which would include lifecycle management opportunities for existing products in the portfolio and capital deployed in our manufacturing plants. And on the latter, we expect to see annual CapEx in the range 3% to 4% of revenue on an ongoing basis, excluding separation costs.

Our third capital allocation priority is really a tie between, A, execution of external growth plans to develop a pipeline of new product opportunities like Jada 2.0 and ebopiprant, and balanced against, B, debt reduction and our commitment to maintaining our BB/Ba2 rating. We are targeting a long-term leverage ratio of below 3.5 times net to adjusted EBITDA.

Turning to guidance now on slide 13, today, we are affirming the guidance that we laid out at our May 3 investor event. We're revisiting basis of presentation. Our guidance both for the May 3 investor event and today is non-GAAP and pro forma as if the spinoff happened on January 1. Beginning with revenue, this is a chart that we showed at Investor Day and there's been very little change. We continue to expect revenue to be in the range of $6.1 billion to $6.4 billion, which is essentially all organic. We do include de minimis partial year revenue contribution from the acquisition of Alydia Health that closed in June.

The biggest component to the year-over-year change in revenue, of course, is the expected LOE impacts. Impacts from LOE were approximately $210 million year-to-date and are primarily related to the loss of patent protection for ZETIA in Japan and NuvaRing in the United States. So far, we have not seen a generic entrant for DULERA, which lost exclusivity in 2020. So, we're improving our full-year estimate of LOE impact to $300 million to $400 million from the $400 million to $500 million that we projected at Investor Day.

As we were careful to describe previously, 2021 is an inflection year for Organon. After 2021, our LOE exposure dissipates to approximately $300 million cumulative over the four-year period 2022 through 2025. Those who attended Investor Day would know that we had said $250 million, but with DULERA now moving out of 2021 and into 2022, that pushes out some LOE exposure into future years.

As far as upcoming VBP exposure, we now expect that EZETROL will most likely be included in the next round of VBP in 2022 instead of this year, as we previously expected, but we don't see that moving the needle on the $200 million to $300 million range we previously expected.

Obviously, COVID is something we're watching closely. Year-to-date impact from COVID was about $220 million. However, as we consider lagging trends in well visits and the effect that that has had on NEXPLANON, as well as potential disruptions from the COVID-19 Delta variant, we now believe the 2021 impact from COVID could be more in line with 2020, as opposed to slightly better as we previously thought. On a yearly basis, we expect foreign exchange translation to be a modest tailwind based on year-to-date currency performance and where spot rates are currently.

Taken on the whole, this quarter's revenue performance is well-aligned with our previous guidance and it continues to reflect the key themes that we've been talking about in our public communications prior to the spinoff.

Looking through the LOE issues that are waning, we are seeing volume growth as we expected, mainly driven by our key growth businesses, women's health and biosimilars. We're also seeing volume growth geographically in China in fertility and Established Brands, ex-VBP.

Turning now to other guidance items on slide 14, we're affirming all of the guidance that we provided at Investor Day. And we're updating shares outstanding, so that it's now a fully diluted number. We expect weighted average fully diluted shares to be about 254 million for 2021.

To reiterate what we said in May, we expect gross margin to be in the low to mid-60s range. We expect SG&A expense to be in the range of mid-20% of sales. We expect R&D expense to be in the mid-single digit range as a percentage of revenue. And what this really represents is mostly R&D infrastructure and a relatively small amount of variable spend on the organic lifecycle management opportunities that we're planning to undertake for products currently in the portfolio. And as we fill out a pipeline, our R&D expense would rise to support these programs. And we expect some of that to occur in 2021, but not by enough to revise the guidance range that we gave previously.

So taking all this together, that would put us on an adjusted EBITDA margin in the range of 36% to 38% for 2021. We expect back half of the year margins to be lower than this range based on phasing of spending. And this is primarily related to delayed spending due to COVID, as well as timing of spending for lifecycle management programs, the integration of Alydia Health and some other investments that we're planning that are intended to drive revenue growth in the future.

Below the line, interest expense for 2021 – again, as if we were a stand-alone company since the beginning of the year – is expected to be approximately $400 million for the year, which reflects our new debt structure as a stand-alone company. Depreciation is expected to be in the range of $100 million to $115 million. And we expect our ongoing non-GAAP effective tax rate to be in the range of 17.5% to 19.5%, with book and cash taxes being roughly similar.

Wrapping up the financial discussion, the franchises are progressing as we expected. And given our outlook for 2021, we continue to believe that we're well-positioned for future organic revenue growth in the low to mid-single digits on a constant currency basis. This will be driven by stabilization in the Established Brands portfolio and continued growth in both women's health and biosimilars, each of which has the potential to grow at low-double digit CAGRs in the intermediate term.

At this point, I'll turn the call back to Kevin for closing remarks.

Kevin Ali

Chief Executive Officer & Director, Organon & Co.

Thank you, Matt. And I just want to stress that we're very early in our journey, but we're off to a solid start. Today, we reaffirmed our outlook for 2021 and we continue to feel very well-positioned to deliver low to mid-single digit growth off of our 2021 base of business.

In closing, I'd just like to say we're building something special at Organon. We're early in the stages of building a unique and differentiated ESG approach in the company. We take diversity, inclusion and equity initiatives very seriously. And we believe our board, which has the most female representation of any S&P 500 healthcare company today, will play a key role in our future success.

When we launched our company back in June, we also launched a commitment to listening and understanding women's healthcare needs throughout the world, so we can find new solutions to address those needs. It is a purpose that permeates throughout the entire company and our culture, and we believe creates value across the spectrum of Organon stakeholders.

Now, we'd like to open up the call and take your questions. Thank you very much.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Your first question comes from [ph] Lisa Slavic (00:29:40) from Goldman Sachs. Your line is open.

Terence Flynn
Analyst, Goldman Sachs & Co. LLC

Q

Hi. This is Terence Flynn. Thanks for taking the questions and congrats on your first quarter as a public company. I was just wondering – two-part question – first, if you could elaborate further on your business development strategy in women's health. I'm assuming Alydia and ObsEva are typical of the deals you're looking for. But maybe you could give us a little bit more color on the universe of opportunities and what that looks like and how you're thinking about the pacing on the forward?

And then the second question I had is just on the outlook for dividend growth. How are you thinking about that or is it simply going to be anchored to a payout of free cash flow? Thanks.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Thanks for your question, Terence. And I'll take the first question, and then pass it over to Matt to deal with the second question on dividends. So you're right. I mean, as we mentioned during our Investor Day, as well as our various equity road show discussions, we're looking at, as we say in kind of baseball parlance, singles and doubles. And ObsEva and Alydia fit perfectly in this kind of area.

But having said that, we've – as I mentioned a number of times, we did a scan a couple of years back and, essentially, we need to update that scan. And we identified probably about 140 assets in various stages of development around the world where we could actually use some of – obviously, some of our balance sheet capital to be able to go out and make some meaningful acquisitions.

So we're working because of the fact that, as I mentioned a number of times, unmet needs are significant out there in a number of different areas for women in areas of significantly in terms of areas specifically to women and those that are predominately affecting women. And so, there's plenty of opportunity for us. Stay tuned. We're in discussions right now and more to come.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

And on the dividend, we thought very carefully about where to set the dividend in terms of balancing our desire for shareholders to participate in the cash flow generation of the business, but making sure that we retain enough cash flow to support our growth programs. So, the target of the low-20 percentage of free cash flow, we think, strikes the right balance. And we will be looking to stick close to that as we roll out into the future. So, we expect that the dividend will grow in conjunction with our growth of free cash flow.

Operator: Your next question comes from Navann Ty from Citi. Your line is open.

Navann Ty
Analyst, Citigroup Global Markets Ltd.

Q

Hi. Good morning. Thanks for taking my question. Could you comment on the COVID recovery on your key products? And can we expect contraception to be offset by fertility in the near term? And then, longer term, do you have any comments for the outlook for fertility in China and the US? Thank you.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Matt, do you want to take that?

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

Sure. So, we've certainly seen a COVID recovery in the business Q2 versus this point last year. And let's remember that this point last year was really sort of the, I think, the depth of the issue in terms of patients accessing healthcare systems – United States and many countries around the world were on lockdown.

So, we have seen a COVID rebound in the business. We've seen it more in fertility than in contraception. As we stated in the prepared comments, fertility patients, for a number of reasons, are more motivated to return to the clinics versus patients seeking to roll – to initiate a rollover contraception. And so, we do think that there is more COVID recovery to be realized in the businesses, depending on the progression of the Delta variant and any other variants that may come. So, that's – I think we've seen some encouraging results in terms of the COVID rebound, both for fertility as well as across solid portions of the established brand portfolio, but we are looking for more as the pandemic recedes.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

If I could just add on to some of the points that Matt made, and I'm sure we're going to get into discussions on NEXPLANON and some other issues down the road. But in terms of fertility, because that was the focus of one of your points in your question, it has significant growth in the quarter and it really anchors our women's health focus. Q2 is 59% growth versus Q2 2020, and year-to-date, we've got 46% growth versus year-to-date 2020. And we're significantly outpacing the fertility market growth. The market is growing at 35% and we're growing at 46%, so very positive sign for our fertility efforts and what we're doing.

And remember that overall behind what's going on here, there's a movement. I mean, I mentioned China and the three-child policy, Japan, and soon, IVF reimbursement soon to begin, France, in terms of egg freezing, as well as same-sex couples reimbursement, more reimbursement from US employers to single parents like in the EU, recognizing the need to address declining birth rate. So, we're very bullish and very focused on fertility. It's an important area of focus for us and we'll continue to see the kind of double-digit growth we always expected from it.

Navann Ty
Analyst, Citigroup Global Markets Ltd.

Q

Thank you.

Operator: Your next question comes from Greg Fraser from Truist Securities. Your line is open.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Thanks for taking the questions. Good morning, folks. On the revenue guidance, can you speak to the pushes and pulls that could get revenue to the high end versus the lower end of the range? What's important to consider for the second half? The pandemic is clearly an unknown, but what are the pushes and pulls would you call out that are important to consider?

And then, my second question is on biosimilars. ONTRUZANT and BRENZYS are facing greater competitive intensity in the EU. I think you'll have some challenging year-over-year comps in the second half for those products. The biosimilars business is an important part of your growth strategy. So, how should we think about growth in the second half? And what will be the key growth drivers for that business ahead of the biosimilar HUMIRA launch in the US in 2023? Thank you.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

So I'll take the first part of the question, Kevin, with the push and pull, high end/low end versus guidance, and you can cover biosimilars. So, we feel very good about our full-year revenue guidance of $6.1 billion to $6.4 billion. The biggest source of variability in terms of where we land in there, I think the questioner pointed it out, would certainly be where the pandemic takes us. We do believe we have a good handle on most other key drivers, whether it's LOE impact, China VBP. So whether we end up at the high end or the low end, I think we'll be – it'll really be driven by the progression of the pandemic and I think where FX rates may go.

Let's not forget, 80% of our revenues are outside the United States and we report in US dollars. So, there can be cases where foreign exchange translation and this is – it's just – it's a reporting impact, not an economic impact, per se, that can just drive our reported numbers, even though we may end up post our expectations in local currency.

Over to you, Kevin, on biosimilars?

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Yeah. So great question, Greg. So just to clarify, we do not have the Samsung Bioepis anti-TNF business in Europe. That is essentially part of Biogen's business there. But what I will say is we are clearly doing well in biosimilars. Q2, we had 35% growth. And year-to-date, it's 23% growth in spite of obviously COVID. But what we see, for example, going forward, is the fact that RENFLEXIS in the US is doing exceptionally well; ONTRUZANT just recently launched; and AYBINTIO has been recently launched in EU where we continue to do well because we have the oncology biosimilars in EU.

And, of course, we have our biggest product potential which is HADLIMA which is the HUMIRA biosimilar that's going to be launching in 2023. We expect to be second on the market with our own citrate free high dose availability which we are very, very bullish on.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Thank you.

Operator: Your next question comes from Charlie Yang from Morgan Stanley. Your line is open.

Matthew Harrison
Analyst, Morgan Stanley & Co. LLC

Q

Hi. Good morning. It's Matthew Harrison. I was hoping that you could just comment more broadly as opposed to just this year but the longer-term outlook on VBP pricing and the impact that can have on the business, especially for NEXPLANON. Thanks.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Sure. I can handle that, Matt. And so, look, we're very, very enthused by the performance in China currently. Q2 we've got essentially 12% reported growth and year-to-date it's 3% reported growth. Remember, four products, key products, the largest batch that we've had were included into the volume-based procurement process in Q4 of 2020. And through the second quarter we already stabilized the business, showing volume growth and revenue growth. We're really excited as well. Overall the retail performance, I mentioned a number of occasions before that the retail focus we started in 2017 seeing that VBP was going to be an issue. And right now our performance in the retail sector in Q2 has grown almost by 30% and already accounts for nearly 45% of our Established Brands business in China.

And I also mentioned fertility. Fertility, by the way, I'll just take an opportunity to say this, that fertility grew 70% in the second quarter. And just as a reminder, the fertility franchise is not subject to volume-based procurement and is a 100% cash pay business. Our portfolio in China right now, 60% of the Established Brands business, 60% of our portfolio have gone through the volume-based procurement process, 10% will not because it's really fertility-driven, 30% is remaining; about 20% of that 30% will go through in 2022 and the remaining 10% will come in the outer years. So we're very diversified.

Remember, in volume-based procurement in terms of China, no single product represents more than 20% of our business. So we've got a very well-diversified business. We have a business that's moving quickly to the retail channel just because we've got experience of it for the last five years. And also we see that the future is essentially – in terms of any exposure that we might have, the URPS potential exposure which potentially happens in 2023 approximately hits can affect about 40% of our business there. But it's been in the forecast discussed during our May Investor Day. It's already folded in. So we feel very good that we're on the way back to really managing the volume-based procurement process in China.

Operator: Your next question comes from Umer Raffat from Evercore ISI. Your line is open.

Umer Raffat
Analyst, Evercore Group LLC

Q

Hi, guys. Thanks so much for taking my questions. Kevin, if a large business development opportunity were to become available, I'm talking something of the scale of, let's say, the Biogen stance on JV or like a large women's health business from one of the pharma companies. Can you speak to your ability to engage in something like that especially early on being a public company? Are you constrained in being able to use [indiscernible] (00:42:28)? That's first.

Secondly, I know there's a lot of investor interest in figuring out what are the true growth drivers that's beyond biosimilars going forward. And one of the points I thought about is what's your ability to engage with Merck on the possibility of using NEXPLANON device IP for substituting other women's health generic products in there to

create new sort of an NEXPLANON 2 and NEXPLANON 3 kind of thing, new offerings using that device given the physician comfort with that device? Can you speak to that in any programs ongoing?

And then finally, where are you guys on the Microspherix versus NEXPLANON IP side? I know you've lost a couple of cases, but it's also been my sense that there's starting to be an alignment. And at least on part of those patents you guys have been able to settle. Should we expect Microspherix to be a nonissue and NEXPLANON from a damages perspective going forward? Thank you.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
A

Thanks, Umer. Let me try to address those points. So from a business development perspective, of course, we're always looking for what we feel is going to be really an important contributor to the type of business that we're doing. We are though executing currently exactly on our strategy, which is essentially, as I mentioned to you before. There are a number of assets out there that are really looking for a home because there are significant unmet needs. And we believe we can start to be an aggregator in some of these women's health assets that are unique in terms of what they provide as solutions for some of the significant unmet needs that women face around the world.

And so, right now, the way that we've executed on that strategy is what I believe is spot on to what we wanted to do. It's really kind of – look, we're two months into our launch and our spin. We've already done two deals. So that really shows our seriousness. But of course to your point, if something really attractive with the right valuations, the right focus, the right marriage, of course, we're going to look at that seriously but nothing of that nature is something that we're considering right now. We're considering more of the same of what you've seen from us over the first two months.

In terms of NEXPLANON raw technology, of course, we're always, we're in very close coordination with our Merck colleagues. And right now we don't have anything in the pipeline in terms of focusing on using that raw technology for anything else than what we're doing today, which is essentially moving from three years to five years is our focus right now in our life cycle management development for NEXPLANON. We hope that that will give us an opportunity to extend the life of NEXPLANON to 2030, which will really make it available to many more women who really need and want something with that long of a horizon in term of efficacy for five years.

Finally, in terms of what's happening in Microspherix, I think we feel very solid and very good. Obviously, I can't comment on ongoing litigation. But we feel very good of our position there and we have a very strong case. And I think, as you said, we'd like to wind that down in the not too distant future, but we feel very good and very confident about where we stand right now with that potential issue.

Umer Raffat
Analyst, Evercore Group LLC
Q

Thank you, Kevin.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.
A

Sure, Umer.

Operator: Your next question comes from Steven (sic) [Steve] Scala from Cowen. Your line is open.

Steve Scala
Analyst, Cowen & Co. LLC

Q

Thank you. In the second quarter, there was a $20 million contribution from other. Can you elaborate on what other consists of? Secondly, has Organon done the studies necessary for your HUMIRA biosimilar to be substitutable? And then lastly, if I might, does Organon have any NMEs in development from legacy Merck in its existing pipeline? Thank you.

Matthew M. Walsh
Chief Financial Officer, Organon & Co.

A

So I can take the first part of that question, Kevin. So the $20 million in other is principally supplied sales to Merck. So as part of the separation, we inherited six manufacturing facilities in their totality. And some of the activity in those sites is related to Merck products, which will be continued under an MSA, Manufacturing Services Agreement. And so, that's what shows up in the other bar.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

And in regards, Steven (sic) [Steve], to your second question in regards to the interchangeability focus. So, Samsung our partner doesn't feel that interchangeability is really the key point right now in terms of what they need to do. And keep in mind, most of the biosimilars right now, up for FDA review ultimately and hopefully approval in the frame that we set, do not also have interchangeability. And it's not really a major issue.

The major issue is really the citrate-free and of course, the high dose focused on citrate-free product availability. That is the key because then you truly become a biosimilar, because obviously the originator, in terms of Humira has obviously citrate-free in 100 milligrams, and essentially that's what we're going to be coming to the market with. And we're very confident that we'll be in the position of entering second.

It's our biggest opportunity, it's obviously positioned – or rather a pharmacy-dispensed product and that is essentially, I think, a good proof point for the value proposition of what biosimilars will bring to the market. And in regards to your last point – in regards to – did you mention enemies to, in terms of do we have something with regards to Merck in conflict in regards to development?

Steve Scala
Analyst, Cowen & Co. LLC

Q

Well, did Merck impart any new molecular entities in your pipeline which are in development? And actually, if I could follow up on the second question, why do you think interchangeability of a Humira biosimilar is not important or why does Samsung believe it's not important? I think most people think it is important. So, if you could elaborate on that as well, that'd be helpful.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

A

Yeah. Sure. Sure, Steven (sic) [Steve]. And so, first and foremost, no, we did not get any new molecular entities in our pipeline from Merck. We're building our pipeline out as I mentioned, there's plenty in the hopper in terms of our business development strategies and focus in terms of what we can do with our cash flow.

And I think the proof point is really in the two deals we've done in the few months that we've actually spun. In regards to why does Samsung believe that interchangeability is not the key focal point, I believe right now that Samsung has a view that they've done their research and their due diligence and the like for example Amgen in

terms of their – they're the first expected to be on the market also does not have interchangeability as part of their focused value proposition.

So it's really about, and again I'll repeat, citrate-free high dose availability is really going to be the very, very key thing. But the key thing for all of us as well for biosimilars business is order of entry. Really anything that you can do to actually be in the first tranche of products that are potentially approved so that you can offer access and choice to patients is really the key focal strategic point of view for what we're doing in biosimilars.

Steve Scala
Analyst, Cowen & Co. LLC

Q

Thank you.

Operator: The last question we had in queue. Thank you, everybody for joining us today. The team looks forward to engaging with you throughout the quarter.

Kevin Ali
Chief Executive Officer & Director, Organon & Co.

Thank you.

Operator: This concludes today's conference call. Thank you all for joining. You may now disconnect.