GSK plc

GSK plc - Q2 2023 Earnings Call

Wednesday, July 26, 2023 7:00 AM

Event Participants

Executives 7
Nick Stone, Emma Walmsley, Tony Wood, Luke Miels, Deborah Waterhouse, Julie Brown, Unknown Executive

Analysts 14
James Gordon, Jo Walton, James Quigley, Emily Field, Peter Welford, Eric Le Berrigaud, Michael Leuchten, Graham Parry, Unknown Analyst, Richard Parkes, Andrew Baum, Simon Baker, Emmanuel Papadakis, Steve Scala

Nick Stone Executive

Hello, everyone. Welcome to our half year and Q2 2023 conference call and webcast for investors and analysts. The presentation was sent to our distribution list by e-mail, and you can also find it on gsk.com. Please turn to Slide 2. This is the usual safe harbor statement.

We'll comment on our performance using constant exchange rates, or CER, unless stated otherwise. As a reminder, following the Consumer Healthcare demerger in 2022 to form Haleon, we're presenting performance and growth from the continuing operations for GSK. Please turn to Slide 3. Today's call will last approximately 1 hour and management presentation will take between 30 to 35 minutes with the remaining time for your questions. [Operator Instructions] Our speakers today are Emma Walmsley, Tony Wood, Luke Miels, Deborah Waterhouse and Julie Brown, with David Redfern joining the rest of the team for the Q&A portion of the call.

Turning to Slide 4. I will now hand the call over to Emma.

Emma Walmsley Executive

Thanks, Nick, and a very warm welcome to everyone joining us today. I'm delighted to be presenting to you all another set of excellent results for GSK. Please turn to the next slide. Sales and profits grew at double-digit levels for the quarter, our sixth consecutive quarter of strong growth. Sales were GBP 7.2 billion, up 11%, excluding pandemic solutions.

Adjusted operating profit was up 12% to GBP 2.2 billion. And adjusted EPS were up 17% to GBP 38.8p. This is further evidence of a sustained step change in GSK's performance, and this momentum supports our decision to upgrade our guidance for the year. Our

performance also demonstrated delivery of the strategic choices we've made to develop the portfolio and the R&D pipeline. New products, notably in vaccines and HIV, all made healthy contributions to growth and reflect the investments we've made to prioritize these parts of our business.

62% of sales are now coming from Vaccines and Specialty Medicines, which we expect to provide durable and profitable growth through the decade. And new products launched since 2017 have contributed to sales of GBP 4.6 billion so far this year, adding nearly GBP 1 billion of distributional turnover compared to 2022. Equally, our General Medicines business continues to perform alongside the other parts of our portfolio. Next slide, please. We are deploying capital in a financially disciplined way to invest in growth and deliver stronger returns to shareholders.

We are delivering on our commitments. And as you can see from the slide, we are on track to hit all the targets we set out in 2021. As you all know, our very first priority to capital remains to invest in continued pipeline progress. And we know this is the key question to shareholders. At the core of our work is an aggressive pursuit for organic pipeline delivery and targeted business development.

We are making good progress on both, and there is more to come. The approval of Arexvy this quarter is, we believe, transformational and set to bring enormous benefit to people aged over 60, who are annual exposure of RSV. Arexvy is spearheading the next wave of vaccine innovation at GSK. This quarter, we presented positive pivotal data for our pentavalent meningitis vaccine, secured regulatory approval for Shingrix in Japan in at-risk populations, and achieved U.S. FDA Fast Track designation for our candidate vaccine to prevent gonorrhea, a bacterium that is considered a high-priority pathogen by the WHO.

And as you could have seen at our recent Meet the Management event, we have substantial innovation to come with potential new vaccines to prevent influenza, pneumococcal disease and herpes simplex virus. This all sits alongside other innovation in infectious diseases like bepirovirsen for hep B and a new portfolio of much-needed anti-infectives. We're also very pleased with the progress we're making in our HIV portfolio. A key aspect here is, of course, to develop the portfolio to replace the loss of exclusivity to dolutegravir, which, as a reminder, is not expected to start until 2028 in the U.S. and 2029 in Europe.

We are well on track to do this. We expect sales from our new long-acting regimens of around GBP 2 billion by 2026. And to add to this, clinical development plans are advancing very well to support new ultra long-acting options launching from 2026. And with these innovations, we aim to replace the majority of revenues from dolutegravir and support profitable growth for GSK well into the next decade. And we're looking forward to talking to you more about this at our HIV Meet the Management Event in late September.

Equally, we continue to make good progress in our business development. Here, we're targeting acquisitions and partnerships to strengthen and complement our core therapy areas to help deliver above and beyond our current long-term outlook. So you should expect to see us keep up probably the same levels and pace of BD as we have in the last 18 months. This quarter, we completed the acquisition of BELLUS Health. They're adding upon our respiratory expertise with the addition of the camlipixant, a Phase III potential best-in-class

treatment for refractory chronic cough.

Our pipeline in broader respiratory is developing well, too, across all 3 product areas, and we're increasingly confident it will be a major source of new long-term growth. Next slide, please. Our focus is to deliver competitive performance and improved shareholder value in the short, medium and long term. With our current momentum and further successful execution of our priorities, we are very confident in our ability to deliver profitable sales growth in all 3 of these time frames. For 2023, we now expect to deliver sales growth of 8% to 10% and adjusted operating profit growth of 11% to 13%.

For 2026, we expect to deliver sales of more than 5% and adjusted operations profit of more than 10% on a CAGR basis. And by 2031, we're confident we will have effectively absorbed any impact from the loss of exclusivity across the portfolio to deliver our stated ambition of more than GBP 33 billion in sales. We know this ambition is significantly higher than current market expectations. And over the next year, we'll continue to bring you more clarity and specificity on our building blocks that deliver profitable results through a series of Meet the Management events, data readouts and a more comprehensive update against our 2021 long-term plan. Let me now hand over to Tony, who will talk you through his latest thoughts on R&D priorities and performance.

Tony Wood Executive

Thank you, Emma, and hello, everyone. It's great to be with you today. Please turn to Slide 9. I'm pleased to report that we're making good progress in strengthening the pipeline and we know there's more to come. Our absolute focus is to develop a robust pipeline that can drive a sustainable, profitable growth.

I see this being achieved through a combination of organic delivery and disciplined business development overlaid with continuous improvement in R&D productivity. This is reflected in my 3 priorities for R&D shown on this slide and in the delivery of our strategy, which is focused across 4 therapeutic areas, and aims to leverage our deep understanding of the immune system and use of advanced technologies. Next slide, please. It's important that we allocate our capital and resources effectively. I think about this in two perspectives.

First, from a therapeutic area standpoint, our priority is to build on our strengths in leadership in infectious diseases, HIV, respiratory immunology and our emerging capabilities in oncology. This is by investing in both organic and targeted business development to deliver first or best-in-class innovation, balancing probabilities of success and sales potential. And we apply the same discipline and returns criteria for both approaches. In addition, we also see platform and data technology-enabled opportunities. Second, from the time perspective, I want to develop partner or acquire vaccines, specialty medicines and technologies with significant commercial potential that can meaningfully contribute to sales and profit growth in the latter part of this decade and beyond.

Ultimately, I want a portfolio of R&D innovation that offers a good balance of risk and return and which can drive growth for GSK above and beyond the ambitious -- the ambition, sorry, Emma just talked about. Slide 11, please (sic) [Slide 12, please]. Our pipeline today comprise of 68 assets in clinical development. Two-thirds of the assets within our development

portfolio are focused on infectious diseases and HIV. In infectious diseases, we're focused on seasonal respiratory viruses, bacterial, fungal and chronic viral infections.

Vaccines are front and center of this effort. Emma has already mentioned Arexvy and some of the innovation that is coming behind it. Our pentavalent meningococcal vaccine candidate recently met all primary endpoints in the Phase III trial and demonstrated immunological effectiveness against a 110 diverse MenB strains. These account for 95% of circulating strains in the U.S. Five serogroups are responsible for most meningococcal infections and no single approved vaccine can yet protect against all 5.

If approved, MenABCWY would do so, offering a simplifying immunization change up and supporting increased vaccine uptake. This is important when you consider that only 30% of adults currently receive full protection from all 5 meningococcal serogroups. We're on track to submit the vaccine to regulators in 2024. Our novel 24-valent pneumococcal vaccine candidate acquired through the Affinivax transaction has also shown very positive immune response across serotypes. We continue to examine potential acceleration options for the 24- and 30-valent programs in infants and adults.

With CureVac, we're looking to disrupt the influenza market and deliver new multivalent combination vaccines using next-generation mRNA technology. Multivalent Phase I and II Zejula and Nucala trials are underway, and we expect data from these towards the end of this year and the start of 2024. In chronic viral infections, in addition to geographic expansion, we're looking at new growth opportunities, Shingrix. These include expanding the population who might benefit from protection to a young adult such as the recent Japanese approval to include adults aged 18 to 49. And we continue to review the potential need for a booster.

Additionally, a growing body of evidence suggests that shingles vaccination may reduce the risk of dementia. And we're leveraging our expertise in herpes varicella zoster virus to develop a promising injectable treatment for the control of herpes simplex virus reactivation. Our plan is to initiate proof-of-concept studies later this year. In anti-infectives, we've now assembled a promising portfolio of new medicines. Gepotidacin, which is stopped early for efficacy and is anticipated to launch next year, has the potential to be the first oral antibiotic to treat uncomplicated urinary tract infections in more than 20 years.

Complementing this is tebipenem from Spero Therapeutics, which, if approved, will provide us with access to a late-stage antibiotic with the potential to treat complicated urinary tract infections. Brexafemme, a novel first-in-class medicine to treat fungal infection, acquired through an exclusive license agreement with SCYNEXIS completes this trio. Bepirovirsen is another potentially transformative treatment, which can help patients achieve a functional cure for chronic hepatitis B. We look forward to presenting data from our Phase IIb trial together later this year. This trial is designed to answer whether interferon is needed to improve the durability functional cure following the hep B treatment.

In HIV, we're entering an important period in our clinical development plans for potential ultra long-acting treatment and prevention options. These spearhead the transition we expect to deliver in the HIV portfolio over the next 5 years. We'll be setting out more detail on this in our third quarter investor event. In respiratory and immunology [indiscernible] in late-stage development of our IL-5 medicine, depemokimab. The addition of camlipixant, a highly

selective P2X3 antagonist, in the treatment of refractory cough also provides us with another asset in Phase III development.

Luke and I expect to be sharing more with you on our plans and opportunities in respiratory before the year-end. In oncology, we are progressing the regulatory submission for momelotinib following U.S. FDA's recently extended review date to September. We're confident this new medicine will help tackle the significant and debilitating medical needs of myelofibrosis patients with anemia. Given the makeup of our current portfolio and capabilities, our approach in oncology is to prioritize the development of novel medicines to treat blood and women's cancers and to explore other potential breakthroughs in immuno-oncology.

Jemperli, our highly effective PD-1 inhibitor, is central to this approach and exploration as a backbone treatment for using combination with other proven or promising therapies is in development. Next slide, please. You'll see how many of the elements I've just touched on are expected to play out over the next 12 to 18 months. I believe these, together with targeted business development and a series of important Phase I, Phase II investment decisions, will lead to a significant progression in this pipeline in the short term. Slide 13, please.

Alongside allocating resources to prioritize and accelerate clinical development, I want us to continue to improve overall R&D productivity. We've made progress. Success rates and cycle times are improving, but more needs to be done. For me, this really means 2 things. First, doubling down on leveraging our scientific capabilities with the use of new platform and data technologies.

And second, developing our partnering and external sourcing capabilities. With AI and machine learning applications now rapidly maturing, access to proprietary data to feed models and generate novel insights is a key strategic differentiator. For example, we recently presented data results for bepirovirsen from the B-Clear Phase IIb trial. This deep, multimodal analysis helped us to develop a clear heterogeneity mapping for hepatitis B, stratifying individuals treated with bepirovirsen into 3 subtypes: a highly enriched response, a mixed response and a nonresponse subtype. Each defined by distinct clinical, urological and molecular trajectories and associated with a number of markers.

These predictive models provide greater precision in existing markers and suggest potential enrichment strategies. We're competitively placed in platform technologies and have laid strong foundations in data technologies. I want us to vigorously scale and build on these foundations to better derisk targets and rapidly test and progress high-quality first-in-class candidates, all with the aim of accelerating and improving success rates of our development programs. In summary, let me close by saying I'm pleased with the progress we've made so far this year and that we have clear plans in place to move forward at pace to deliver on our key objectives for R&D and support the overall growth ambitions at GSK. I'll now hand it over to Luke on Slide 14.

Luke Miels Executive

Thanks, Tony. Please turn to the next slide. Pleased to say that quarter 2 was another quarter of continued strong commercial execution with growth across the business. All three of our

product groups, Vaccines, Specialty and General Medicines, were up in the quarter with growing contributions across all three regions. Please turn to Slide 16.

In quarter 2, we delivered GBP 7.1 billion of sales, up 11% versus last year, excluding pandemic solutions. In Vaccines, strong growth of 15%, excluding pandemic solutions, was supported by Shingrix, which was up 20%, and Bexsero, which was up 18%. Shingrix delivered another record quarter of sales, and it's the sixth consecutive quarter of growth. In the U.S., we've now reached the most motivated consumers with about 32% penetration of eligible people receiving at least 1 dose. Moving forward in the U.S., we're resourcing for success by raising awareness about the importance of shingles prevention, especially among [teens] who are less motivated to get vaccines.

We remain confident in the U.S. opportunity and believe we can reach flu-like penetration of around 60% to 60% -- 65% over time. Ex U.S. remains an important growth driver for Shingrix and represented 46% of the revenue in the quarter. Shingrix is now available in 33 countries with most -- with less than 3% penetration, indicating the potential for further expansion in these populations.

We've got unconstrained supply of strong global demand, and we continue to retain high value with U.S. like pricing as we launch in [private pay settings] globally. In Specialty Medicines, including HIV, which Deborah will speak about shortly, we increased sales by 12%, excluding Xevudy, to GBP 2.5 billion. Our market-leading blockbuster specialty medicine, Benlysta and Nucala, continued to deliver double-digit growth. Benlysta was up 19% in the quarter with sustained growth across all major markets with further opportunity to drive increased penetration in both SLE and lupus nephritis with about 25% by penetration in the U.S.

and other key markets. We're focused on life cycle management opportunities for Benlysta as we explore further indications including systemic sclerosis associated with interstitial lung disease, which will be important for patients as well as having a continued halo effect across the entire product. Nucala was up 15% in the quarter and remains the first and only biologic approved in 4 eosinophilic diseases with new indications driving growth and differentiation. The severe asthma continues to grow in the U.S. with opportunity for Nucala to drive buyer penetration with our clearly differentiated profile in EOS patients.

And we look forward to having COPD data in 2024. In oncology, sales were down 3%, in line with expectations. However, Jemperli continues to be a growth contributor and we're excited about the potential for our PD-1 as the development program investigates the opportunity to help all patients with endometrial, ovarian and potentially other indications. Our General Medicines portfolio grew 8%, driven primarily by Trelegy, which is up 30% in the quarter. Trelegy continues to have a best-in-class profile across -- access versus competitors, and there's a leading share of voice with key specialty HCPs like pulmonologists and allergists.

Considering this strong Q2 and H1 performance, we now expect Specialty Medicines to grow high single digit and high General Medicines to grow at low single digit in the full year. We still expect Vaccines to grow around same. Please turn to Slide 17. We're very excited about the upcoming launch of Arexvy. We believe Arexvy's profile and recommendation to support our market leadership and position with multibillion annual sales potential.

Additionally, the CDC has now adopted last month's ACIP recommendation and is being communicated broadly to health care providers, an important step that sets clinical guidance and establishes the trigger for paid coverage. Launch is now underway as we speak, and we have a clear understanding of what is required for successful commercial execution. We're also building on our relationship with retailers, given our expertise in the older adult population for Shingrix, and we're playing to our strength using our deep respiratory expertise and our experience [indiscernible]. We've now shipped doses to distribution centers, and we look forward to the impact that the support and medicine will help prevent the severe consequences of RSV in the U.S. and globally as we also prepare to launch this season across Europe.

With that, now let me hand over to Deborah on Slide 18.

Deborah Waterhouse Executive

Thanks, Luke. Our HIV business delivered sales of GBP 1.6 billion in the second quarter of 2023, growing 12%. This growth was primarily driven by demand, which contributed 8 percentage points of growth and U.S. pricing favorability, which contributed a further 2 percentage points of growth. Our performance benefited from strong patient demand for our oral 2-drug regimens and long-acting injectable medicines, which now constitute more than 40 -- more than 50% of our total portfolio.

This demand helped grow our global market share by 2 percentage points versus last year. The inventory build that we saw in the U.S. at the end of last year have now materially burned, and we don't anticipate any further significant burn this year. Dovato delivered GBP 430 million in the quarter. Market performance reflects HCP belief in Dovato, which is now our #1 selling HIV medicine.

We were also pleased that dolutegravir received U.S. FDA pediatric exclusivity in the quarter, which extends the dolutegravir loss of exclusivity in the U.S. by a further 6 months to April 2029. And as a reminder, Europe is -- to April 2028. And as a reminder, Europe is 2029.

We aim to further consolidate our leadership in pediatric HIV by following a similar approach with our foundational medicine, cabotegravir. Turning to Cabenuva. Sales for the quarter were GBP 176 million, reflecting strong HCP demand with high levels of market access and reimbursements across the U.S. and Europe. Growth is being driven by positive sentiment towards the SOLAR data presented at CROI earlier in the year and strong commercial execution.

It is particularly pleasing to see that more than 70% of Cabenuva sales are originating from competitor regimens. Moving on to prevention. Sales of Apretude, the world's first long-acting injectable for the prevention of HIV, delivered GBP 36 million in the quarter. And we're pleased by the growing momentum across the U.S. We were delighted that early this week, the European Medicines Agency granted positive opinion for this medicine.

With more than 100,000 new infections every year across the continent, we very much look forward to the approval of Apretude, which has the potential to significantly reduce the transmission of HIV in Europe. We're encouraged by the progress of our pipeline, which is focused on innovative long-acting regimens. We have 3 clear target medicine profiles to

provide the world's first self-administered long-acting regimen for treatment and to provide ultra long-acting regimens with treatment and prevention with dosing intervals of 3 months or longer. I'm pleased to confirm that next month, we shall begin our Phase IIb study of cabotegravir in combination with our broadly neutralizing antibody, N6LS, which offers the potential for ultra long-acting dosing. We are very excited about the potential of these medicine profiles, but we'll be ready to [indiscernible] in 2024.

We remain very confident in our ambition to achieve a 5-year mid single-digit sales CAGR to 2026. And our strong Q2 performance means we are in a position to raise our outlook for 2023 from mid-single digit to a high single-digit growth rate. And with that, I will hand to Julie on Slide 19.

Julie Brown Executive

Good afternoon, everyone. I am delighted to be here at my first set of results as the CFO of GSK. The biopharma industry is incredibly special to me. It's where I spent most of my career, and it is a sector that can create enormous value for patients and shareholders. GSK is a company that I've long admired and it has a clear purpose to positively impact the health of billions over the next decade.

And I'm really pleased to be part of the team that is going to deliver this. As this is the first time speaking to you and before we cover the financials, I wanted to take the opportunity to highlight 3 areas of focus that are going to be important to me as CFO. So first disciplined capital allocation with 2 clear priorities: to invest for growth and to deliver improved returns to shareholders. Second, partnering with Tony to enhance returns on investment and improve R&D productivity with a strong focus on resource optimization and efficient funding. And third, identifying sources of business efficiency to fund investments and deliver a competitive P&L.

So first, turning to the next slide in capital allocation. Our first priority is investment in the business, driven towards development of the pipeline through both organic and targeted business development. We will also invest to support new product launches. My intention here is to be laser-focused on prioritizing and accelerating investments in those assets and technologies which will help us to deliver growth. I intend to achieve this through an increased focus on ROI for organic and BD-related investments.

And this will include an assessment of the market opportunity, first-in-class potential and best-in-class potential [indiscernible] sales, probability of success and expected financial returns. Through returns to shareholders, our primary mechanisms of cash distributions will remain through the delivery of aggressive dividend. And last year, the payout ratio of 40% to 60% over the cycle was established. And we expect to maintain dividends within this range as earnings increase over time. For completeness, in the event of a surplus, excess cash would be returned to shareholders using the most efficient mechanism available.

However, we do not expect excess cash in the medium term, given our priority is to invest in growth. And finally, and very importantly, we remain committed to maintaining a balance sheet with a strong investment-grade credit rating. Taken together, I believe this represents a sensible capital allocation framework for GSK consistent with our strategic priorities and

supportive of our commitments to deliver profitable growth through this decade. Turning now to the quarter. As I cover the financials, references to growth are at constant exchange rates, unless otherwise stated.

And I will focus my comments on adjusted results. So starting with the income statement. Sales increased 11%, excluding COVID solutions, and were up 4% overall, reflecting the strong delivery that Luke and Deborah have covered. Operating leverage, primarily in COGS, drove adjusted operating profit growth of 11% with the margin increasing to 30.2%. Excluding COVID solutions, adjusted operating profit grew 12%.

Turning to the reported results. The growth in total profit was driven by strong operating performance and favorable contingent consideration liability remeasurements. Please turn to Slide 22, and turning to margin dynamics. As mentioned, the adjusted operating margin was 30.2%, a 200 basis point increase versus the prior year at constant rates. Excluding the impact of COVID solutions, the margin increased 20 basis points.

Cost of goods sold decreased, primarily reflecting reduced sales of low-margin Xevudy in Q2, which resulted in a gross profit increase of 11%. Excluding COVID solutions, COGS increased in line with sales, with a neutral gross margin impact, with favorable mix and efficiencies offset by higher freight and energy costs. SG&A reflects investment behind product launches such as Shingrix, geographic expansion, HIV and preparations for Arexvy's imminent launch. We expect the SG&A growth to reduce in the fourth quarter as investment levels stabilize and to be broadly in line with sales growth for the full year. In R&D, there was increased investment across a range of early and late-stage programs, including a number that Deborah and Tony discussed earlier.

Our royalties benefited from Gardasil, Biktarvy and Kesimpta. And there was a 70 basis point adverse move from foreign exchange. And next slide, please. So earnings per share benefited from lower net finance expense and noncontrolling interests and now turning to the adjusted compared with our total results. Next slide, please.

So overall, total and adjusted operating profit were similar in the second quarter at GBP 2.1 billion and GBP 2.2 billion, respectively. In addition to CCL remeasurements, the main other adjusting items of note were within divestments, significant legal and other. And this reflected dividend and distribution income received, including Haleon dividends and the fair value movements of Haleon shares, which was partly offset by significant legal charges. Legal fees primarily reflected increased charges to Zantac, of which the vast majority relate to prospective legal costs for the defense. Next slide, please.

Cash generated from operations was GBP 1.9 billion in the first half, GBP 2 billion lower than the prior year. And the key drivers are similar to those covered at Q1 and relate to the Gilead settlement and timing of Xevudy collections received last year together with pension payments and increased working capital this year. There was no change to our expectation that 2023 cash generated from operations will be slightly lower than 2022. And we remain committed to our 2026 projection of more than GBP 10 billion. Net debt increased to GBP 18.2 billion, reflecting the free cash outflow and net acquisition cost of BELLUS Healthcare, partly offset by disposal of investments, including the monetization of part of our equity holding in Haleon.

And turning now to guidance on Slide 26. We have delivered a very strong first half. And as Emma mentioned, we are upgrading our guidance for the year. As a reminder, all of this guidance excludes the impact of COVID-19 solutions. We now expect sales to increase between 8% and 10%, up 2 percentage points.

We expect adjusted operating profit to increase between 11% and 13%, and adjusted earnings per share to increase between 14% and 17%. Within sales, we are maintaining our full year Vaccines expectation of a mid-teens percentage growth and are upgrading our expectations for Specialty and Gen Med. We now have anticipated Specialty Medicines and HIV within it to grow a high single-digit percent and for Gen Med to grow a low single-digit percent. And turning to phasing, and firstly, on sales. We expect that the second half growth will be below the first half [in full] by the comparatives.

We would also expect sales growth to be slightly higher in Q3 relative to Q4. And secondly, on operating profit, we expect that the second half growth will be stronger than the first with a broadly similar growth rate in each quarter, primarily reflecting SG&A growth expectations as mentioned earlier. Next slide, please. In summary, our business is performing well and with strong momentum. I look forward to connecting with you and updating you on our progress and continued delivery towards our '26 and '31 goals in the quarters to come.

With that in mind, Slide 27, shares how we plan to keep you informed in four key areas: execution, portfolio, capital allocation and investor events. Execution shares our major earnings reviews. The portfolio component builds on the R&D catalysts shared in Tony's presentation. Capital allocation has been clarified further today. And the Investor Relations program shows how we plan to provide you with the building blocks underpinning our pipeline and the opportunity to meet the management to two more events this year.

The first will focus on HIV in September, followed by respiratory and immunology in the fourth quarter. We will also continue to run a comprehensive program of meetings, participation in investor conferences and updates from key medical events. And thank you. And with that, I will hand back to Emma.

Emma Walmsley Executive

Thanks, Julie. It's so great to have you with us. Turning to Slide 29, please. We continue to build trust by delivering in the 6 key areas we prioritized for ESG performance. This quarter, we made progress on several fronts, but I want to highlight one in particular.

Although more than 2.5 billion people will reach this decade, the majority will be through our infectious disease portfolio of vaccines, antibiotics, antivirals and global health for us. And so we were delighted to see new third-party fund announced with regard to M72, a tuberculosis vaccine candidate, discovered and developed by GSK into Phase III development. This could potentially [indiscernible] the first new vaccine to help prevent pulmonary TB in more than 100 years. It is a true testament to GSK's vaccine scientists and our ability to partner with others to develop innovative global health assets in an economically viable and sustainable way, with more than 10 million people falling ill and more than 1.5 million people dying from TB every year and increasing evidence of drug resistance. Successful development of this vaccine could have a profound impact on [indiscernible].

Final slide, please. So in summary, we are seeing strong momentum in our performance with continued delivery of competitive sales and profit growth. We remain very focused on continuing to progress our pipeline through organic development and targeted complementary business development. And our progress is providing us with high confidence to deliver our outlooks and ambitions to shareholders through the decade. And with that, let's move to the Q&A with the team.

Nick Stone Executive

Thanks, Emma. [Operator Instructions] We'll take our first question from James Gordon at JPMorgan.

James Gordon Analyst

James Gordon, JPMorgan. I'll keep to one. My question is about Shingrix in the U.S. So I think the sales declined 10% this quarter, although maybe so flattish when we adjust for stocking. But I saw you've refined the Shingrix global guidance, so it's now high teens this year.

I think it was double digit before. And Luke made some comments about having reached the most motivated patients in the U.S. and further penetration increases, but that sounds like maybe that's going to be tougher in the less motivated patients. So the question is, where are we on Shingrix and U.S. growth specifically?

Could we now be running out of road for the U.S. growth and it's going to be more ex U.S. growth, but the U.S. is maybe sort of flat this year and then could even decline? Or is Q2 a bit of a blip in the stocking and other one-off factors and there's still plenty of U.S.

growth to come?

Emma Walmsley Executive

Obviously, we're still very ambitious. The scale and reach of Shingrix, Luke, do you want to [indiscernible]?

Luke Miels Executive

Sure, James. I suspect he's probably not the only person with that question, so I'll take a little bit longer to cover all those points. So the short answer is not yet. I mean we've covered in past calls, there will be a point which we're entering now, but will need to work harder as we've got this -- what's essentially a long arithmetic growth curve. But yes, I'll just -- I'll take it a little bit to outline the dynamics because it's very much a non-retail effect right now and, as you said, with some stock movements.

So for retail first, we actually saw an 8% growth or up 8% versus last year, and that was pretty much driven by 65-year-old individuals coming in following the removal of co-pay linked to the IRA. And it's interesting, in Q4 and Q1, we added about 2% to the total vaccination around each time. So we now have a penetration of around 32% on the latest data we have [indiscernible]. If you then sort of subtract that, that's about 80 million more people to go, if we were to get to 100%. And we add around 4 million people who turn 50 each year.

The other important element on stocking is we actually changed the rules in terms of how

much stock wholesalers could hold. So we have two categories: Category A, Category B. Historically, Shingrix has been classified in Category B, which just gave wholesalers more room and more flexibility in terms of the volumes that they hold. We've now tightened that up. We are trying to remove some of this volatility.

You remember last year, we had stock movements which were 1.3 and 1.8 and down to 0.9. So far this year, we're pretty tight in the range of 0.6 to 0.7. Expect it will go up a little bit at the end of Q3 in the flu season, but we're trying to keep a tighter call on that. So that hasn't affected well. Now if we go to the non-retail, which is the important component in the U.S., and this is the key shift.

So historically, non-retail has been around 45%, 50% of the business. But in Q1, that went down to 34%. And in Q2, it's around 31%. And it's very specific. We have a very small number of key customers who are now approaching 60% of the target population and their vaccination.

Now we have about 197 other key customers that we can work for. So I guess the glass half full look at this is that we can get to the types of penetration that we're targeting in these centers, and that's an opportunity with the other one. So you're right, we do need to work harder to get to those less motivated patients, but we've always known that's coming and we've got plans to do that. If we look outside of the U.S., just to conclude, we try to explain historically that we [indiscernible] U.S., which is sort of down on that curve. We're now starting in Europe.

And we're very early days in markets like Canada -- China. And as we said, we were about 3% penetration if you exclude the U.S. and Germany, which are ahead of the curve within the penetration. So we're in good shape overall. And I think we look forward to updating you on Q3.

Emma Walmsley Executive

Thanks, Luke. And the other point to emphasize is, as Luke referred to, the cost of reaching deeper into the U.S. obviously goes up. And actually, in the other markets we're in because we don't have advertising and because price has been successfully globalized and that it remains a very appealing business in other lines of immunizations, which, of course, we're now adding to the RSV [indiscernible].

Nick Stone Executive

Next question is from Jo Walton at Crédit Suisse.

Jo Walton Analyst

Yes. I would like to ask a question about IRA and two aspects of that. I wonder if you have a view about increased volume in anything other than vaccines given the change in patient co-pay going down? And also if you could talk about penny pricing and how we should think about that. You have some old products, which will have accumulated very large rebates, which, in theory, would become a problem next year.

We've seen the [indiscernible] companies talk about it. How are you going to handle that in

respiratory?

Emma Walmsley Executive

Well, I'll come to later on that, but you're absolutely right. There are some really good things about the IRA that we're very supportive of the co-pays and [moving] in vaccines is important for our portfolio. There are some other things alongside others in the sector we're concerned about in terms of unintended consequences. And two parts of our portfolio, HIV will be more like in '25. And then in Gen Meds from next year there is some impact, four of which is explicitly absorbed in our guidance and in our outlooks.

So you'll see some volatility there. But Luke, I don't know whether you'd like to comment more on the specifics in established respiratory.

Luke Miels Executive

Sure. I mean, Joe, you may mind in terms of some effects in terms of compliance, I mean we see patients drop out of products like Trelegy in terms of that historical coverage gap. So that should help with volume. As Emma said, there's other aspects to the program that we're less than adult and we need to see how that affects. In terms of MCAP, we've got a very clear listed products exactly, as you said, that had pretty intensive discounting and historical price increases, which have been ahead of inflation, and there has been [indiscernible] effect.

I mean the total exposure, this is just total revenue, not impact when we really stressed this, about USD 700 million. So that's [flowed on] HFA, [flowed on] DISKUS, ADVAIR HFA, ADVAIR DISKUS, SEREVENT, and LAMICTAL and the biggest of those is LAMICTAL

Now we've had a lot of warning, this is coming, and we're working in the U.S. has done a great job in terms of developing authorized generics, partnerships. We have options to divest selected products and where we can't bring an authorized generic or we are unable to divest of course, we can [indiscernible] to adjust that. So that's a collection of the process that we're doing to protect the bulk of that business.

Nick Stone Executive

So the next question is from James Quigley at Morgan Stanley.

James Quigley Analyst

So maybe a question for Julie [indiscernible] one of her comments. So you mentioned sort of building a competitive P&L. So what is your definition of a competitive P&L? And what sort of focus -- what will be the focus areas to generate that competitiveness in terms of margin ranges or growth potential? And then the -- are there any sort of early areas that could drive efficiencies or levers that you can use to get you into these competitive ranges?

Emma Walmsley Executive

Straight to you, Julie.

Julie Brown Executive

So in terms of -- I see a competitive P&L as one that's operating to full capacity and making optimal use of the resources in the business and capital allocation in the business. And I think progress, the progress has been made in GSK already following the separation with the future ready program. I mean, clearly, at the moment, we're in the launch cycle with a number of important medicines and vaccines being brought to the market, as Luke and Deborah both mentioned. As we move beyond this, of course, we will continue to look for efficiencies, and we do anticipate once we're through that launch cycle that SG&A will grow [indiscernible] in sales, thereby improving that particular margin.

And working with Tony closely because, obviously, I've been in the pharma industry for a long time and worked with R&D for a long time. Clearly, investment and productivity and resource allocation in R&D is critical to a pharmaceutical business. So as you can imagine, I will spend some time looking for continuous improvement and opportunities to fuel business efficiencies to fuel further growth.

Nick Stone Executive

So next question comes from Emily Field from Barclays. Okay, can I propose to take the next question then from Peter Welford .

Emily Field Analyst

Oh, no, can you hear me? Sorry, I didn't get the pop up. I didn't get the pop up, I apologize. Sorry. So I wanted to ask a question on flow vaccine.

I know that you had previously guided for a down year, but that's supposed to be down 20%. If you could give any color on what the driver is for that. And then I believe on the pipeline slide, you indicated that we could get an update on the go-forward plans for the mRNA seasonal flu vaccine? And if you could just give any sort of high-level thoughts on what we could expect from that decision in the back half of this year?

Emma Walmsley Executive

Okay. Thanks, Emily. I think you said on flu. So I'll come to -- I mean, as you know current flu business is in, let's call it, not almost modern technology platform, and we are expecting a decline in [indiscernible] on why? You see that, but once again, to reiterate our overall outlook back overall remains very strong for the year.

And then perhaps then you could update, I know we're excited about potential doublet. Luke if you go out with mRNA.

Luke Miels Executive

So basically, you've got a comparative issue as the demand around the time of COVID, of course, was very high. And so that's -- there's pressure there. And the fact is there's a lot of doses around there, but people are very motivated to discount topline, so we're seeing pricing pressure. In terms of volumes, we expect around 43 million doses this year versus around $51 million that we sold in 2022. So our goal remains to evolve this technology, and I'll hand over to Tony.

Tony Wood Executive

Yes. So first of all, I mean, as I said, we're now moving with the mRNA partnership and into -- and COVID into evaluation of multivalent options. We continue to be encouraged by the data that we see there and that move into Phase I and Phase II studies, we expect in the case of both instances, and we'll see be dashed on those towards the end of the year and at the beginning of next year. Probably the only other thing I would add is that I'm sure you followed this well. The field continues to encounter difficulties in [times] with regards to coverage, particularly in these strains.

And what I'd say at this point is our studies are designed to account for on the stream coverage. I'm looking at a broader range of antigens. So all of that will come together when we have an opportunity to update you in more detail at the beginning of next year. We're very pleased with the progress on the platform.

Nick Stone Executive

So our next question is from Peter Welford at Jefferies.

Peter Welford Analyst

I want to come back and apologize to it, but be just U.S. Shingrix for a minute, just to try and understand the cadence here that we're talking about. I mean presumably, the retail segment is typically the segment that we would anticipate to increase towards the end of the year. So just trying to understand, in that segment, you're saying demand is still robust. But presumably, we will see the usual sort of detailing that you do together with blue?

Or is there any sort of issue, I guess, with [indiscernible] perhaps taking over a priority there going into the flu season for the retail channel this year. And for the nonretail, just trying to understand. So the issue is that there's a large, the majority of the non-retail segment has yet to reach that 60% to 65%, but it's becoming -- could you talk about what is the challenge perhaps to [debt] doctors there? Is it coverage? Or is it as insurance coverage?

Or is it just getting these people back in to see the position? What is exactly the sort of the ceiling there with the doctors, please? .

Unknown Executive Executive

Sure. So Peter, I'll start with non-retail first. So we've had a couple of very, very large players that we intensively worked with, its natural when you've got momentum, you try and go with that. And we really wanted to see how high the penetration can get. We still expect those large centers to keep vaccinating and our end is to go beyond 60%.

But the curve does tend to flatten out at 60%. Now if we think long term, this is why I'm personally fascinated with the relationship that we've seen in the well study around vaccination and Shingrix and a potential relationship with Dimension, we're going to be very busy with life cycle work on that one, both prospectively and retrospective analysis. There are another 197 key customers that we have that are in the 30s or a range from sort of 30s to 60s that we are now putting more work behind it. We also pulled back on the primary care promotion on Shingrix in these centers and concentrating on Trelegy to give that

[indiscernible] as an experiment to see if PCPs will fall.

We're now switching that team back to Shingrix. So that's all pointing in the right direction. It's more a case prioritization and just moving that up, these larger centers put a flag in a system, and we saw [indiscernible] really moving. So we just need to do the hard work to pick up the other ones now, and I feel very confident we can do that. In terms of retail, you're right, there is -- there's still a seasonal relationship, and we expect that to continue.

It's not as extreme as it was in the first couple of years of Shingrix, but it's still exists. The unknowns, there's no push on PERLA booster this year, but we don't know what affect that is, that has been a drag historically. But as you correctly point out, we're going to be very busy with Arexvy targeting the high-risk individual, which is a subset of the Shingrix target universe. Let's say we get some more color. I fortunately don't have a crystal ball, but I remain very confident about the demand of this product in the U.S.

in '23.

Emma Walmsley Executive

And just to remind everyone, again, ex U.S. and German we're less than 3% penetration. So there is no mention [indiscernible] for this asset, and it's an asset that we [indiscernible].

Nick Stone Executive

So our next question comes from Eric Le Berrigaud of Stifel.

Eric Le Berrigaud Analyst

Just a question to get more clarity in terms of cash flow development. We're now getting in terms of earning growth into the double digits, and you're raising the guidance here, but still guiding in terms of cash flow declining this year. Could you maybe give us a little bit more details about the push and pulls to make the difference between earnings growth and cash flow decline even though we go beyond the Gilead settlement and the COVID impact and whether getting into '24 and beyond, we might see cash flow development more in line with earnings.

Emma Walmsley Executive

Well, over to you, Julie. And remember, we're reiterating our '26 outlook for operating cash flow.

Julie Brown Executive

So this year, clearly, we've had an influence of a number of factors with the cash flow. A couple of things happened last year that have obviously inflected the comparator. So last year, with the cash flow, we had the Gilead settlement that occurred at the beginning of the year. And then we've also had Xevudy receivables coming in last year. This year, the cash flow has been depressed somewhat partly by movements in working capital and also which we expect to resolve by the end of the year.

And also, we've had an additional pension payment that's been made this year, which was

reasonably sizable over GBP 350 million. So there are some one-offs you may call them relating to the cash flow. This is why you see the GBP 2 billion swing in the first half. But we are maintaining the guidance for the full year for cash flow, which is basically to be slightly lower than last year. The major reason you do see this difference usually are cash flow rating is very much towards the second half.

We normally have around 70% to 75% of the cash coming into the second half of the year. Last year it was very unusual. It was 50-50 because of the things I mentioned.

So that's why you're seeing the difference. In terms of 2024, obviously, we'll guide when we come to that at the end of the year. But you can be sure that we will care for cash. We'll be very focused on cash conversion and the translation of profit into cash. You can see us paying a lot of attention to those as we go forward.

Nick Stone Executive

We have the next question from Michael Leuchten at UBS.

Michael Leuchten Analyst

Question RSV and Luke's comment on prioritization, please. So I guess the ACIP recommendation could have been a little bit stronger than it was. Just wondering how you reacted to that? Will you throw more commercial resources at Direct fee? Or is the plan executed as it was?

Emma Walmsley Executive

Thanks. I know it's [indiscernible] bit of color to that.

Luke Miels Executive

Sure. Look, I think on my Christmas wish list, it would have been for a similar label. That's the label we've got -- but I think to put it in perspective, our strategy has always been to focus on this progress individuals to naturally would engage in that type of discussion with the health care provider, our regular visitors to the pharmacy because they're polypharmacy. And we have market research that clearly says that. And if you look at our label, that secondary claims, the 94% efficacy, et cetera, really plays to our strength.

So I think at the end of the day, it doesn't have an enormous impact in the first couple of years.

We are now actively with [indiscernible] generating the data that the ACIP would want to see, and we're confident that we can bring that. So I think if we look in the medium to long term, we'll see this a fully supported similar access process for these vaccines. Our discussions with insurance are very, very encouraging. There's also been some really good work published by our friends in New York that looked at rates of RSV greater in hospital setting, particularly to use [indiscernible] in those tests, and they're looking at. It's really an under-diagnosed by a factor or to.

So the demand is there, the willingness to recommend is there. So we remained encouraged and the pricing of imports is higher. I think we have to see the full effect in terms of the multi-

season label.

But again, for these high-risk patients, I think this is more of a reassurance and also, arguably, let's just move this out of the seasonal color that we would normally typically have with flu because you've got that longer time frame in terms of courage. So net-net, I think we remain very excited as Emma said. We are very much looking forward to a scientific battle with Pfizer, and it's something that we relish. And in the end, it's going to be mean that physicians and pharmacists are better informed if patients are going to get a better vaccine.

Nick Stone Executive

Next question from Graham Parry of Bank of America.

Graham Parry Analyst

So actually, I just wanted to follow up on, I think a couple of people asked effectively if you can grow Shingrix in the U.S. I'll just throw that to Alex. I don't think it's been answered and then actually ask my question, which is on Zantac. So with the Gilead settlement, you showed a willingness or even a desired settle cases in California, but is that still the attitude that you have towards the upcoming case in November. And now the same lead plaintiff attorney is representing the plaintiff both in California and the Delaware cases with any settlement of the entirety of the [indiscernible] litigation now need to include a Delaware settlement as well?

Emma Walmsley Executive

Well. We'll come to Luke see whether he wants to add anything more to he's already used [indiscernible] on the U.S. But in terms of Zantac we remain very confident in our position. We continue to be guided by the science the evidence sustained in place. We've got a dedicated team managing this.

We'll continue to defend ourselves vigorously. We obviously won't comment on our specific legal strategy ahead of its execution. Happy to be where we are and we'll keep everybody updated as we progress through. Obviously, knowing that we've got Delaware coming in the new year. So nothing more to add than that.

He is shaking his head with nothing new to add on Shingrix. So back to you Nick.

Nick Stone Executive

We take the next question from Rajesh Kumar at HSBC, please.

Unknown Analyst Analyst

Just on the capital allocation piece. You suggested that you're going to focus on deals as well as investing organically in R&D. So could you run us through some criteria you look at when you deploy capital when you pick between R&D versus external investment, how do you compare the 2? What are the internal metrics you look at? And if the management below the top management incentivized similarly for doing deals versus organic investment?

Emma Walmsley Executive

Yes. So I'll comment on that and then see if Luke wants to add on further. But -- it should be really clear in our capital allocation framework that our #1 priority is the [indiscernible]. And as you saw both reduced and from Tony's slides, that's about the pipeline and our launches. And within the pipeline, it is organic and inorganic.

I mean we all know this across the entire sector. I think about half the pipeline is posted outside. That number is probably going up across the sector. And we've been really pleased with the reset of our balance sheet to create the capacity to do that and have had a very focused track record of executing against deals reasonably swift pace, particularly over the last 18 months, so you should expect to see it will be the same. I think the most important point is because it's part of the way we do R&D, our BD team reports into Tony, there is -- we've been very thoughtful about the incentive system and the goals that we set in terms of pipeline progression to keep it neutral regardless of whether it's sourced internally or externally because you're absolutely right.

. And then there was a slightly perverse incentives around that, which aren't helpful. And our criteria are unchanged, and I think we laid out explicitly on Tony's opening slide. We like to look for assets to the best of all persons. We look at ROIs, NPVs.

We look at contribution to sales growth, particularly in the latter half of decade and beyond. We went across the balanced portfolio of risk across all therapeutic areas. We're obviously focused more on investing in our specialty and vaccines pipeline, but also in technology platforms that will allow us to continue to improve productivity. So that's why we like to see the tech enablement of what we bring through. The really important point is that we're got this whether internal or external regardless of TA, we use the same set of criteria.

So I don't know if [indiscernible] Julie Brown.

Julie Brown Executive

Just an extra point. I think I mean we have got also a very rigorous governance process that runs through both BD assets, we get together regularly looking at the BD pipeline as well as the organic pipeline. And as Emma mentioned, one of our jobs we see as being very important is also to accelerate the key assets. So we identified the key assets. We look to accelerate them.

We looked to ensure that they've got the right resources to do that and that we remove any blocker that could be there in the organization. And finally, we also review assets, whether it be BD or organic for success. So we do post deal reviews also. So there's a very rigorous process around this.

Nick Stone Executive

Next question from Rich Parkes at BNP Paribas.

Richard Parkes Analyst

So I just wanted to push you a little bit more to talk about your expectation for the RSV launch based on the initial outreach. I think with the need for places looking uncertain, and I think the market's skeptical on your previous Shingrix-like target, but given higher pricing, clearly, it

could be a more meaningful opportunity midterm if you can drive rapid uptake. Looking at consensus, I think we got GBP 180 million of sales this year and growing to 570 next year. I just wondered if you could give us your thoughts on whether you see potential to exceed those numbers? Or is the weaker ACIP recommendation and maybe lower vaccine that take your factoring into flu vaccine going to be a headwind to that.

I know you've not upgraded the vaccines guidance despite that higher pricing. So does that moderate your expectations in terms of volume.

Emma Walmsley Executive

Thanks. Well, I mean, first of all, I'll start and then I'll come to Luke on any additional comments. But there is absolutely no change to our outlook, which was reemphasized again or meet the management update on infectious diseases that we see the potential of this to be around GBP 3 billion of sales. So in that sense, it's a multibillion asset. I think we've been clear right from the beginning that we didn't expect the start.

We're at the same rate as Shingrix just for the simple fact or awareness to see what that competitiveness for an on-space in there. But also, as you know, we had a very specific recommendations from ACIP [indiscernible] as well as the [indiscernible] initial sort of supply, we are a long way from dealing with here. We're also taking a different pace of launching in most of the countries across the world. We don't guide for individual quarters of sales, but we will likely comments on some more details around the price as well.

Luke Miels Executive

I think there was no solution for RSV historically. So it didn't really make a lot of sense systems to focus on. And then as you saw covered with PCR testing, ultimate was in the company test and better understanding the character and prevalence of RFC emerged. So I think we're in a very different place than we were a couple of years ago. And we -- as we start to promote it and educate the others and pharmacists, and pharmacists can be very enthusiastic about this product.

I think that's a very favorable kind of ambition. There's a heavy overlap with, if you look [indiscernible]. And of course, the Shingrix population and the [indiscernible] population. I've said in the past, and I think it will be a steady build that the people will be very strong. And this is outstanding data for something that's very impactful the health care systems and individuals.

So I think we'll get there. And the dot we've generated so far is [indiscernible]. Pricing wise, again, we went in ACIP with the [call] of 270 to 295, and we've been able to keep within that 280. So I think our credibility with ACIP is in house through that process and the reception we've received so far for payers and pharmacy change has been very encouraging. So that's probably all I can say at this point, I very much look forward to updating everyone at Q3.

Nick Stone Executive

Next question is from Andrew Baum from Citi.

Andrew Baum Analyst

In relation to Trelegy, we're expecting it to be included in the IRA price negotiation list being enacted in 2027. I'm curious as to how Luke is thinking about the ability of GSK to claw back the rebate in order to mitigate the impact of the list price reduction. My understanding is that PBMs cannot exclude a drug once it's been selected for price negotiations. Do you think you can take away the rebate? Or do you think that the PBMs will make you pay by creating hurdles to other products in your portfolio?

And then just following up on an earlier question in relation to the impact of the out-of-pocket cap in driving increased volumes. To what extent do you think -- because still the patients are going to have to pay $2,000 out of their own pocket, how meaningful do you think that really is in getting patients off your patient assistance program on to pay drugs? Or do you actually think $2,000 is still a real barrier for many patients and therefore, the volume impact isn't going to be that meaningful?

Luke Miels Executive

Yes. Andrew, I think $2,000 is still a large amount of money for many people, particularly older individuals. But it's an improvement. It's more predictable for those patients. So I don't see a massive adjustment in some of our systems program, particularly in oncology and areas like that.

In terms of Trelegy, I mean, Q4 this year, we'll have a better idea in terms of how CMS is defining those first [poppy] drugs and how it's going to be managed. But we have, as you said, a very high IRA rates of Trelegy already. I think PBMs probably did more your second scenario is more likely to be a reality. And I think we'd be -- we're very rational to make that assumption. But we're obviously starting to think about rational [indiscernible] and initiating discussions with them.

I think the other fact with Trelegy is where you'll see a generic emerge at some point because the technical challenges that we can see in closing in how medicines are validating that for a relative part is not simple as we've seen with that bet. So I think that's also another factor which we're starting to look at.

Nick Stone Executive

Next question from [indiscernible]

Unknown Analyst Analyst

Question to Deborah on [indiscernible] HIV. Can any [indiscernible] performance in Q2. Just whether you can talk to that? Was that growth in the third quarter will reflective of underlying demand? Or are there anyone off to be aware of in modeling sales in the second half of this year and beyond.

You also highlighted that together two drug regimens, long-acting represent, I think you said around 50% of total. So interested in to see whether that run rate at this point is what you would have expected and the long-acting also lean particularly, you behind in line or ahead of those internal expectations at this point in the year. I squeeze in the quick one just to remind

us of the time lines for your 3 monthly dosing formulation.

Emma Walmsley Executive

Well, obviously, we're extremely pleased with the performance of [Biktarvy] this year and be able to upgrade our outlook on it and not least because of the innovation that we pioneered on coming through so strongly. So Deborah if you want to add.

Deborah Waterhouse Executive

For me to say we're really pleased with the performance of our HIV business in the quarter really strong underlying growth for both our loyalty drug regimens and our [indiscernible] injectables, and that is absolutely being driven by demand. So let's go into Cabenuva it's for demand. We have seen really positive demand for our products for people who are living with HIV and we noticed this is set to continue because we know that many doctors' offices have got people on waiting list particularly in the U.S. to be started on the drug. So it's a really strong underlying demand for people with.

We expect that to continue -- and this, in turn, gives us confidence that we can build this market, and we can deliver greater and greater share of this market through our long-acting [indiscernible].

In terms of expectations, it's ahead of where we expected. If I'm completely honest to be 51% of our overall portfolio in, our overall 2 [veterans] and long acting is ahead of expectation. We're really delighted by the underlying demand and particularly the long-acting injectable uptake from Cabenuva. It takes a long time to build the market and you win this market on your own. So you always wonder how much will it take, how you unlock each stage of the journey, each side you face.

And actually, the answer is yes, we can. We're really optimistic, really optimistic about this opportunity. In terms of the pipeline, I mean, we'll talk more about this at the media management session in September, but what we've said is that we're looking to target an automating version of [indiscernible] so ultra-long-acting average treatment plus from 2027 onwards. We're making really good progress with our reformulation of cabotegravir because that's going to be the backbone to the first wave of our innovation trend treatment. And so what you've probably seen on some of the slides that Tony presented was starting to move forward the company partners is being maturation inhibitor, be it [indiscernible] or be [indiscernible].

And so we're kind of moving those assets forward so that we can make a choice in 2024 of the regimen that we will take forward. And so the date that we've given in our previous investor update and, but we hope to be able to give you a little more specificity when we do the [meet] management in September. But very optimistic position to be in both from a pipeline and a forward perspective in the HIV space.

Emma Walmsley Executive

Great. Thanks, Deborah. Well, I guess there are still a few handful more questions, so we'll keep going and try and give us [indiscernible] myself.

Unknown Executive Executive

Just one correction or one clarification. The patent expiry or LOE controlling is 2027, but where IRA infact is 2028. Just want to make sure [indiscernible].

Nick Stone Executive

Yeah. Simon Baker from Redburn.

Simon Baker Analyst

Going back, turning to Slide 13 on R&D. Two related questions, so one really. Firstly, on the reduced cycle times, could you give us some idea of how much of that is down to therapeutic mix? And how much is underlying reduction in non-vaccine R&D times? And also on the probability trend, you show a nice trend improvement in Phase 2, 3 and beyond probabilities of success.

Normally, that is matched by a reduction in success rates in Phase 1, i.e., you are killing projects earlier. I wonder if you could give us an idea how that trend has evolved over time?

Emma Walmsley Executive

[indiscernible]

Unknown Executive Executive

[indiscernible] In terms of your first question with regards to a cycle times, obviously, there's a component of vaccines in that. However, we are seeing cycle times coming down, particularly across our late-stage portfolio. So a contribution from both. And then in terms of success rates in Phase II, of course, all we want to do throughout the portfolio is beginning to take attrition earlier and earlier. And one of the things that we're driving coming from our focus in human genetics and functional genomics and of course, the benefits that we get in focusing in infectious diseases is to be able to take attrition on an efficacy terms much earlier than the first time in human.

So I'm expecting -- or rather what we see for the future is the preservation of Phase II success rates and is being accounted for by earlier attrition than that necessarily in first time in human. We're very much more focused on the quality of agents driving survival in that stage.

Nick Stone Executive

Next question from Emmanuel Papadakis from Deutsche Bank.

Emmanuel Papadakis Analyst

Perhaps just a quick follow-up. I think, Luke, you said the -- in response to the earlier question around rebates offsetting price negotiation, you said the second scenario. Could you just clarify what you meant by that? Do you mean you think you will be able to reduce rebating to offset that price reduction? And then the question I wanted to ask is just a moment on the delay in the PDUFA.

To what extent do you think any BELLUS will now be diminished in demand by the delay given the emerging data we've seen on anemia benefit with [Momelotinib]? And to what extent indeed then is [Momelotinib] quarterly run rate of GBP 20 million or so, actually a better guide to how we should be thinking about the launch?

Luke Miels Executive

Sure, Emmanuel, I just think we're going to have pressure and it's getting difficult to evade those structures, which I think is my understanding of vendors two options. So I would expect a high pain scenario versus the low plan scenario with Trelegy [indiscernible] and into other products in the portfolio. But Again, we're looking at options to offset that, and I think that we're making good progress there. In terms of [Momelotinib] I think the BELLUS will still be there. It's really interesting.

Some of the recent market research we've got, it's quite current some of the numbers just for interest. I mean [indiscernible] and fulfills an unmet need. . This was quite interesting around 60% of patients present with anemia within 1 year of diagnosis and about 46 needed transfusion. And the other interesting statistics, which fits our strategy is about 2/3 of them are on that 10 to 5-milligram dose of [Momelotinib].

But in terms of [indiscernible] I don't think it's an accurate analog because really, their label is within that platelet subgroup versus the broader anemia group. There has been some, obviously, some credit posters, et cetera, presented that the NCCN guidelines, if you look at the minute they declined to review that broader recommendation.

So that product is very much anchored in a low -- below 50 platelet group, whereas we have a much broader opportunity, we believe, with [indiscernible]. We'll wait and see what the FDA or excited to turn to the label. We've built the business case for the deal on a second-line label -- second line in India. Hope that helps.

Nick Stone Executive

Last question. So over to Steve Scala at Cowen.

Steve Scala Analyst

Can you hear me?

Emma Walmsley Executive

We can.

Steve Scala Analyst

In adult RSV, how has your success in contracting thus far compared to your expectations and versus what you think Pfizer has accomplished to date? Is your potentially superior data given the edge versus Pfizer? And if not, then why do you think that's the case?

Emma Walmsley Executive

And so in recognition that we are in a competitive commercial situation, I'll let Luke answer

the final question.

Luke Miels Executive

Steve, we are encouraged, but it's happening right now. So literally, as we speak. So we'll have more news to you in Q3 of this one. Sorry, I can't tell you anything more.

Emma Walmsley Executive

Thanks, Luke. Well, once again, thanks, everyone, for joining us. We've been very pleased to report another excellent quarter of performance on strong sales and earnings growth, driven by new product sales, and it's been HIV and vaccines, ongoing progress in our pipeline. The approval of the world's RSV vaccine, [indiscernible] and of course, upgrading guidance and with this momentum behind us, a lot of confidence in delivering our short, medium and long-term targets, and we really look forward to keeping you informed over the quarters ahead. Thanks all.

Bye.